S. HRG. 103–707

ACCESS TO MEDICAL TREATMENT ACT

HEARING

OF THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

ON

S. 2140

TO PERMIT AN INDIVIDUAL TO BE TREATED BY A HEALTH CARE PRACTITIONER WITH ANY METHOD OF MEDICAL TREATMENT SUCH INDIVIDUAL REQUESTS, AND FOR OTHER PURPOSES

JULY 22, 1994

Printed for the use of the Committee on Labor and Human Resources

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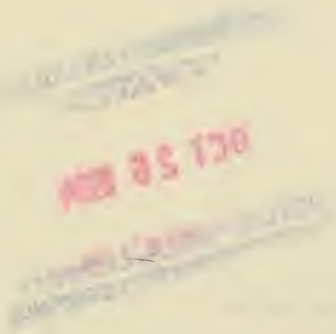

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ACCESS TO MEDICAL TREATMENT ACT

FRIDAY, JULY 22, 1994

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The committee met, pursuant to notice, at 9:12 a.m., in room SD-192, Dirksen Senate Office Building, Senator Tom Harkin presiding.

Present: Senators Harkin, Pell, Simon, Hatch.

OPENING STATEMENT OF SENATOR HARKIN

Senator HARKIN. The Committee on Labor and Human Resources will come to order. The hearing this morning will focus on S. 2140, the Access to Medical Treatment Act, the chief sponsor of which is Senator Tom Daschle from South Dakota and of which I am a cosponsor, which would expand consumer access to alternative medical treatments.

As I said, S. 2140 was introduced by Senator Daschle, and Senators Pell, Grassley, DeConcini, and myself are all cosponsors thus far. It is fairly straightforward. It would allow an individual to be treated by any licensed health care practitioner with any method of medical treatment the individual desires so long as there is no evidence that the treatment is a danger to the patient. The provider must inform the patient if the therapy has not been approved by the FDA and give them a full and accurate reporting of past treatment results.

S. 2140 was developed because even though our current health system addresses certain health problems extremely well, there are many diseases for which we can offer no remedy or the conventional therapies available have low success rates and are extremely expensive. People suffering from these diseases and conditions deserve the right to receive alternative treatments.

The time and expense currently required to gain FDA approval of alternative treatments effectively excludes many alternative therapies from ever being reviewed. This has the unfortunate effect of denying patients important contributions of individual practitioners, scientists, smaller companies, and others who do not have the financial resources to complete the FDA approval process. S. 2140 would change that.

This morning, we will hear from individuals who have benefited from alternative treatments. Some of what these witnesses say may sound out of the ordinary, but let's keep in mind that as recently as 50 years ago nitroglycerin was considered a crazy idea for treating heart attack victims and antiseptic techniques were dis-

missed as quackery because many did not believe that germs caused disease. Medical science has always been skeptical of the unknown.

Last year, as chairman of the Health and Human Services Appropriations Subcommittee, I held a hearing on the Office of Alternative Medicine, which I had earlier worked to have established at the NIH. At that hearing, we discussed a survey on the use of alternative medicine published in the New England Journal of Medicine. This survey found that in 1990 people made 425 million visits a year to alternative providers. Nearly 1 in 3 Americans was using nontraditional therapies. So, clearly, consumers are speaking with their feet and their pocketbooks. They want more choices and they want more control over their health and their health care.

Most everyone knows someone who has had an experience with an alternative treatment. In some cases, people may have sought out an alternative therapy that did not work for them and which, in fact, may not have been a valid treatment at all. But on the other hand, we also know people, like some of the witnesses who will testify before us today, who had the courage and the persistent and, in many ways, the stubbornness to search for a treatment which made the difference between life and death, and health or chronic illness.

I would like us to resist the urge to make overarching generalizations. Alternative medicine, like conventional medicine, comes in many different forms, and treatments must be considered separately. Many people are skeptical of any nonconventional treatment, but we can not ignore the fact that there are many cultures in the world that have developed successful treatments for health problems that may be beneficial.

For example, herbal remedies administered by a naturopath or other trained provider, or acupuncture administered by a trained acupuncturist, are likely to have similar results for Americans in the 1990's as they have had for other people over the centuries in other cultures. Just because a technique isn't part of our conventional medical system does not mean it has little or no therapeutic value. In fact, there is much conventional medicine that has not been scientifically proven, but these treatments, like herbal medicines, have been used so often with the same result that we accept them.

I believe it is important in this age of technology transfer and global communications to make use of valuable medical treatments regardless of how old they are or who first developed them. I also recognize that many treatments and therapies merit scrutiny. We must work to achieve a delicate balance between allowing people access to promising therapies and protecting consumers from harmful products and from expensive, ineffective treatments. I know Senator Daschle and the other cosponsors of this legislation share my desire to work with experts to assure that the bill does the best possible in this balancing regard.

I look forward to hearing from all of our witnesses and to benefiting from the range of views they will provide. I am hopeful that the knowledge gained from this hearing will give us the basis for any needed improvements that may be needed in the bill so that it can be moved forward through the legislative process and hope-

fully made a part of the health care reform bill that, again, hopefully we take up here within a couple of weeks.

With that, again, I will yield to the chief sponsor of the bill, my good friend, someone who understands that consumers ought to have more choices, my good friend, the Senator from South Dakota, Senator Daschle.

Opening Statement of Senator Daschle

Senator DASCHLE. Mr. Chairman, thank you very much for your holding this hearing and for your leadership and your partnership in this effort. I am very grateful to you for the tremendous demonstration of interest that you have shown throughout this process.

I am eager to hear the testimony of the witnesses that you have invited as we begin to explore the issue of access to alternative therapies. The catalyst for both of us in this area has been Berkley Bedell, a former Congressman from the 6th District of Iowa. Congressman Bedell, a very good friend of both of us, will be participating in the second panel this morning and I would like to extend a special welcome to him.

The Access to Medical Treatment Act attempts to address what I see as a fundamental problem inherent in our current medical system; namely, that the time and expense required to obtain FDA approval of a treatment serves to discourage all but large pharmaceutical companies from undertaking this endeavor. As a result, many low-cost and potentially beneficial treatments developed by smaller companies and individuals with lesser resources are thwarted.

The challenge is to increase access to alternative treatments without putting the consumer at risk. The Access to Medical Treatment Act attempts to open up the system and allow opportunities for the trial of alternative treatments that may prove to be extremely effective. It also endeavors to enhance consumer freedom of choice in the realm of medical treatment.

I want to emphasize, however, that this legislation is not intended to dismantle the FDA, undermine its authority, or appreciably change its current medical practices. It is not meant as an attack against the FDA or its approval process. The heavy demands and requirements placed upon treatments before they gain FDA approval are important, and I firmly believe that treatments receiving the Government's stamp of approval should be proven safe and effective.

The intent of my legislation is merely to extend freedom of choice to medical consumers under controlled circumstances. I recognize the dangers implicit in trying to increase freedom of choice in this area and I take them seriously. We must not lose sight of the importance of protecting the consumer from dangerous and fraudulent treatments. That is why this bill is armed with strong consumer protection provisions.

In essence, this legislation addresses the fundamental balance between two seemingly irreconcilable interests—the protection of consumers from dangerous treatments and unscrupulous charlatans that would advocate unsafe and ineffective medicine, and the preservation of the consumer's freedom to choose alternative therapies.

Some may say that reconciling these two interests is an impossible task, but I don't believe that. In any case, the complexity of this policy challenge should not discourage us from seeking to solve it. I am convinced that the public good will be served by a serious attempt to reconcile these contradictory interests, and I am hopeful that the discussion generated today will help point the way to its resolution.

I welcome debate on this legislation and I encourage constructive suggestions for improvement. Our health care delivery system should be more receptive to alternative treatments. Individuals, especially those who face life-threatening afflictions for which conventional treatments have proven ineffective, should have the option of trying alternative treatment so long as they have been informed of the nature of the treatment and are aware that it has not been approved by the FDA.

I am sensitive to the fact that how we open up the system has important ramifications that must be thoroughly explored. Congress is currently engaged in an historic effort to reform the way health care is delivered in this country. That challenge has engendered emotional debate about the security of the status quo and the potential threat of change. It has also stimulated new perspectives on the means to assure cost-effective and comprehensive health care to all Americans.

I am hopeful that the Access to Medical Treatment Act will have a similar effect by generating serious discussion on the practical effects of venturing into this new area of medicine and charting a course that will allow greater use of alternative therapies in a prudent and controlled manner. While it may be premature to take that step in the context of comprehensive health care reform in 1994, I am confident that it is a step that will and should be taken in the near future.

So again, Mr. Chairman, I appreciate the opportunity to examine these issues through the hearing process, and thank you for allowing me to participate.

Senator HARKIN. Senator Daschle, thank you, and again I thank you for your strong leadership on this issue.

I would recognize Senator DeConcini for any opening statement that he might make.

Senator DECONCINI. Mr. Chairman, thank you, and not being a member of the committee, I would be glad to yield to Senator Simon, who is a member.

Senator SIMON. Go ahead.

OPENING STATEMENT OF SENATOR DECONCINI

Senator DECONCINI. I will be very brief. I want to thank you, Mr. Chairman, for holding these hearings on a very, very important piece of legislation and Senator Daschle's initiative.

I personally have had some experience with alternative medical treatment, nothing too severe, but very helpful at the time, and I am a big believer that we have to move with the times and provide these alternatives to the consumers. At the same time, as Senator Daschle and you point out, we have to be careful that we do not open the door to fraud and misbehavior that would infringe on and damage the American public.

This bill assures patients are fully informed. The bill assures minimal consumer safety protection. For example, the patients must be informed if there are adverse side effects. It streamlines the approval process in FDA for medical care so it has become more efficient. That is no easy task. Having dealt with the FDA on a number of cases dealing with patents, it is very important that we listen to them, but it is also important that they offer ways in which this can work because I am a firm believer that it can. Patients can control their decisions about medical treatments which are not conventional and not mainstream. So I hope we can empower patients with this legislation.

I also compliment former Congressman Bedell, who has led this charge and has a personal experience, as well as others who will testify today. So, again, Chairman Harkin, thank you for your leadership in conducting these hearings and thank you for letting this Senator be a part of them.

Senator HARKIN. Senator DeConcini, certainly you are welcome to stay and take part in the questioning of witnesses who are here, as your schedule permits. Again, I thank you for your help and your support in this entire area of looking at alternative medicines and therapies.

I yield now to the Senator from Illinois, Senator Simon.

OPENING STATEMENT OF SENATOR SIMON

Senator SIMON. Thank you very much, Mr. Chairman. I want to commend Senator Daschle first for his leadership in sponsoring this. I might point out that the portion of the bill that would have overridden State laws regarding licensing boards has been taken out of the bill. I think that was a matter of some concern for some of us.

Second, I want to commend you. Your works in terms of seeing that NIH looks at alternative methods of solving some of our problems, I think, has been an important step forward.

Our aim is clearly to protect the public. Senator Daschle used the words "in a prudent and controlled manner." I think that is the way we have to proceed. I am concerned, and this bill doesn't solve this problem; it moves in the direction of helping us look at alternatives.

I am going to use my friend, Berkley Bedell, as an example, and I think he will forgive me for doing that. His lyme disease problem where he found that the whey of milk helped him—the difficulty is you can't patent that. No one can make a huge profit out of that. Our system is geared toward encouraging developments where there is a great profit for someone.

What we have to do somehow is to devise a mechanism so that if there is some answer for problems, whatever the nature of our problems may be—where there are answers that are inexpensive and don't give a huge profit to anyone, we can also use them. That is a problem that this bill doesn't address, but is one that I think at some point we ought to be looking at a little more.

I thank you, Mr. Chairman.

Senator HARKIN. Thank you very much, Senator Simon. That is a very valid point. Of course, one of the things we are trying to do in this bill is to provide better access to different therapies, and

perhaps those that maybe aren't those that might engender a huge profit for a company, but could be widely dispersed. This bill might really get at that problem that you addressed right there by making these more widely available and used by people as long as they are, of course, not inherently dangerous. Therefore, some of the effectiveness of these might be proven. I share that concern with you, and hopefully that is one of the things we tried to address in this bill.

With that, let's call our first witness to the table. We thought we would start off with the Food and Drug Administration. We have Mary Pendergast, Deputy Commissioner and Senior Adviser for the Food and Drug Administration. If you could come up to the table, do you have someone with you, too?

Ms. PENDERGAST. Yes, I do. Thank you.

Senator HARKIN. If you would, whoever you want to bring to the table just introduce them for the record, I would certainly appreciate that. Again, welcome to the committee. We have a copy of your statement. It will be made a part of the record in its entirety. We would ask you to please summarize it, if you could, in as short a time as possible. We are trying to limit people to about 8 minutes, but figure 10 minutes, anyway. So if you could encapsulate that and make the major points, again, we welcome you, and if you would please introduce the people you have with you for the record?

STATEMENT OF MARY K. PENDERGAST, DEPUTY COMMISSIONER AND SENIOR ADVISER TO THE COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MD; ACCOMPANIED BY DR. BRUCE BURLINGTON, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION; DR. ROBERT TEMPLE, OFFICE OF DRUG EVALUATION; AND DANIEL MICHAELS, OFFICE OF ENFORCEMENT, FOOD AND DRUG ADMINISTRATION

Ms. PENDERGAST. Thank you. Let me introduce my colleagues: Dr. Burlington, the head of our Center for Devices and Radiological Health; Dr. Robert Temple, the head of our Office of Drug Evaluation; and Mr. Daniel Michaels, the head of our Office of Enforcement.

Thank you for giving us an opportunity to discuss with you today S. 2140, the Access to Medical Treatment Act. In my brief oral statement, I will limit my comments to only two areas: first, FDA's commitment to speed promising new drugs and medical devices, and, second, the three major concerns the FDA has with S. 2140.

We share your concern about getting useful medical treatments to patients. When it comes to the testing and review of medical products, the FDA doesn't care whether a medical product is labeled alternative or mainstream. We don't care whether the product was synthesized in a state-of-the-art laboratory or found in the Brazilian rain forest. It makes absolutely no difference to the FDA whether the product was first used abroad or in the United States, whether it was developed recently or was used centuries ago as a folk remedy. All we care about is that the product be studied, and studied scientifically, so that we can truly know whether or not it works. We do this for no other reason than to be sure that patients

are not harmed by experimental therapies of no proven value. This scientific process applies to and works well for all of these products.

In recent years, the agency has implemented various procedures to bring life-saving therapies to patients faster through single-patient IND's for which any patient is eligible, treatment IND's for which large groups of people can be eligible when they have serious and life-threatening illnesses, and parallel track where we make drugs widely available while the studies are going forward.

In addition to providing access to some unapproved products, we have also worked hard over the last several years to increase access by speeding our device and drug approval processes. We have expedited those review procedures. We now have accelerated review procedures, and we have also instituted management changes.

We are also trying to encourage research, especially research into alternative therapies or for that small researcher you are concerned about. We work with the Office of Alternative Medicine. We just had a 2-day workshop on acupuncture and there is going to be one on botanicals in December. Through our orphan products program, we give grants to the small researchers to get them started when a big company isn't picking up a promising therapy.

Mr. Chairman, the FDA is dedicated to making promising new therapies available just as soon as possible for those patients who might otherwise have no treatment options and no hope, without compromising the public health. But we recognize that consumers are benefited by FDA's ability to make health and safety decisions based on science. Our concerns about S. 2140 are grounded in the fact that it abandons that scientific process.

First, as structured, 2140 would needlessly expose patients to dangerous products. Unlike current law, S. 2140 does not require a company to test a drug or device in animals before it is tested in humans. There will be no teratogenicity tests, which kept thalidomide away from pregnant women in this country and their fetuses.

Although S. 2140 contemplates allowing the use of only those products that show no evidence of harm, this requirements is virtually meaningless without a requirement for scientifically valid testing. Moreover, the safeguards in this bill will not protect patients. Health care practitioners will be ignorant of the dangers or side effects of products because no systematic studies of dangers or side effects will have been carried out. It is extremely difficult for any individual health care practitioner to judge whether a particular side effect results from the treatment or from the underlying disease, and there will be no true informed consent. If history is a guide, 80 percent of the treatments offered will not work or will be harmful.

Our second major area of concern involves the impact of 2140 on research and development across the board. Although many experimental alternative medical approaches have been in wide use, little, if any, information may be known about their safety or effectiveness for a particular disease or a particular group of patients. It is already difficult to carry out the clinical trials necessary to assess scientifically the safety and effectiveness of alternative approaches because they are so widely used. This difficulty will only increase if S. 2140 is enacted. We have little doubt that the broad

access to unproven therapies permitted by this bill would seriously and significantly impede the development of conventional drugs and devices as well.

Our third area of broad concern has to do with old-fashioned quackery. Under current law, health fraud is a significant problem. Because S. 2140 has no requirement for testing effectiveness, it would provide a green light for charlatans and opportunists to prey on sick and uninformed and frightened consumers.

Mr. Chairman, the FDA shares with the sponsors of S. 2140 the goals of providing consumers of medical products broad freedom of choice and increased availability of treatments, whether conventional or alternative. However, we do not believe that S. 2140, as presently structured, will succeed in that goal. We fear it is going to have precisely the opposite effect. That is why we urge you to maintain and build upon the current statutory scheme. Work with us to take advantage of the many innovations we have carried out to increase access to promising therapies, and help us find new ways to speed new treatments to the sick without losing sight of their need for protection. Although our concerns today are significant, we would like to work with you. We share your goals and the goals of the sponsors of this legislation.

Thank you.

Senator HARKIN. Ms. Pendergast, thank you very much for collapsing that statement down into a shorter span of time. I appreciate it very much. I have been going through your testimony. As you know, I just received it this morning. I like to go through these testimonies the night before so that I have a better idea of what they contain.

Ms. PENDERGAST. As Mark Twain once said, if we had more time, we would have written a shorter letter.

Senator HARKIN. I beg your pardon?

Ms. PENDERGAST. We apologize for the length of our testimony.

Senator HARKIN. I was just making some notes here. You said you have accelerated certain approval procedures and then you mentioned acupuncture, and I am aware of the problem with the needles and how they are classified. Again, I think this is a classic example. Here is a medical procedure and medical devices that have been used for 1,000 years, maybe more than that, in another culture, in China.

I remember when acupuncture was first talked about here 20 years ago, people laughed about it. They said it was voodoo. Well, we now know that it is not and we do know that it works, and people have been doing it for 1,000 years. Yet, what are we going to do, reinvent the wheel again? I mean, why don't you send people to China and find out how they do it and what they use it for, and adopt some of their methods over here? Why do we have to reinvent the wheel on acupuncture? Why do we have to go through all this time and all this money when it is being used in another country—not just one, but in many countries, very successfully, and has been for many, many centuries?

Ms. PENDERGAST. We are working closely with the Office of Alternative Medicine on acupuncture, and we are working closely with the acupuncture community to help get information to the FDA.

Dr. Burlington, perhaps you could explain.

Dr. BURLINGTON. Thank you. Mr. Chairman, we wish to look seriously at acupuncture and, as Ms. Pendergast said, we are in the process of working with the community to look at the classification. We need to look at the evidence and we need to organize that and we need to have it brought to the agency in order to support a reclassification petition.

We have such a petition which we are working with the manufacturers, practitioners, and licensing boards on, and intend to address this, but we are required to reach a conclusion that there is a basis for supporting reclassification.

Senator SIMON. Will the chairman yield?

Senator HARKIN. Will you just tell me how long has the review of acupuncture taken, how far is it from completion, and how much is this study projected to cost?

Dr. BURLINGTON. Mr. Chairman, I don't have all that information in front of me. I will have to supply some of that to you for the record. I do know that the original reclassification issue was brought to the agency in 1978. At that time, it was felt to be extremely controversial and in light of that controversy it was retained in class III. We have begun over the last 2 years additional discussions with the community. We can get you, for the record, additional information.

Senator HARKIN. I do want to have the answer to my question on how long it has taken—you have said since 1978; we know that—how far you think it is from completion, and what has this cost thus far and what is it projected to cost, if you will submit that.

[The information referred to was not received at the time of printing.]

Senator HARKIN. Did someone try to interrupt me?

Senator SIMON. Yes. I would just like to follow through because I think acupuncture kind of is illustrative of the problem. We would not be talking about acupuncture right now if Scotty Reston of the New York Times hadn't been in China and needed an emergency appendectomy. All of a sudden, acupuncture was on the front pages of our newspapers, and so many people have been helped by this process that was being held back from the American public.

There is a—I would use her name, but maybe she would prefer that I not, but a widely known journalist who lives in Washington who was just devastated. I remember she wanted to interview me for a magazine article and I had to go to her home. She was unable to leave her home. She finally tried acupuncture and she is back on television, back out among us. If it hadn't been for Scotty Reston focusing us on this, that would have been denied her and a great many people. I think somehow we have to be able to get these other alternatives out to people better.

Ms. PENDERGAST. We don't disagree with you. I think as Senator Harkin pointed out, 20 years ago people might have laughed. Well, it was in 1976, which is close to 20 years ago, that the FDA was first asked to look at acupuncture. So at that time, it was not known, it was not well characterized. People didn't understand it, and that is why the agency's first step was the cautious one.

Today, it is a different story. That is why we are working with the Office of Alternative Medicine. We are working with the acupuncture community and we are thinking with them about lessening the strictures so that it would be downgraded to a class II special control. So I think, you know, history catches up with us. We learn things, and I think that it also evidences our new activism in terms of trying to get things to people.

Senator HARKIN. I have a comment I want to make. Let me just make one. I am going to yield to Senator Hatch on that. Again, I think there is a mind set here. I understand how these things happen, but there is a mind set, I think, maybe in FDA, as there is within the established medical community in America, that if it doesn't conform to how we feel and how we think and how we are structured, it must not be right and we have to make it conform to our structures.

When acupuncture was first brought to the FDA, it was well known among many doctors and scientists in this country that it had been used very effectively in China and other countries for centuries. Rather than going over there and examining what structures they use and how it was done, it had to somehow conform to what we believed. It is sort of like if it isn't American medicine, it must not be very good and you have got to prove that it works within our structures before it can be acceptable.

That is one of the real problems I have not just with FDA, but with the basic medical structure in this country. We are not looking at other countries that are equally as advanced as we are in many of these areas—maybe not in other areas, but at least in some of these areas—and trying to bring those to this country. That is the problem I have with that kind of a response.

Ms. PENDERGAST. Part of the difficulty here is that the Food and Drug Administration doesn't do the testing. It is the obligation, the way the law is currently structured, that the person who would like to sell the product does the testing. But you have to understand the FDA doesn't care if the testing is done in China. We accept foreign data. It is not necessary for acupuncture to be reproven in the United States. The scientific evidence of its effectiveness has to be gathered somewhere. If the Chinese are doing trials or keeping track of their patients and all that sort of thing, that is acceptable. It doesn't have to be done in the United States.

Senator HARKIN. I am going to recognize Senator Hatch for two things, and first of all thank him for his tremendous help in this area of alternative medicine and supplements and everything else that we have worked very closely on. He has been a great leader in this area and I would just yield to him for an opening statement, if he wants, and for follow-up questions.

OPENING STATEMENT OF SENATOR HATCH

Senator HATCH. Thank you, Mr. Chairman. I just want to start off by thanking you for holding these hearings and for your leadership on this important piece of legislation.

It has been my privilege to work closely with Senator Harkin on key legislation that gives the American people greater access to dietary supplements, and so it seems only natural that we would

work together on this proposal which gives the American people greater access to medical treatments.

There are a number of witnesses today I would like to just welcome here, as well as our representatives from the FDA. I ask that the rest of my statement be put in the record.

[The prepared statement of Senator Hatch follows:]

PREPARED STATEMENT OF SENATOR HATCH

Mr. Chairman, I would like to start off today by thanking my distinguished colleague from Iowa, Senator Harkin, for his leadership on this important piece of legislation. It has been my pleasure to work closely with Senator Harkin on key legislation that gives the American people greater access to dietary supplements. So, it seems only natural that we work together on this proposal which gives the American people greater access to medical treatments. I would also like to recognize several of our witnesses, including Alex Schauss and Michael Janson, with whom I have worked closely on S. 784, and, of course, one of the leaders of this movement, and the best advocate for alternative medicine there is, Berkley Bedell.

Mr. Chairman, I am pleased to participate in today's hearing on an issue that a growing number of Americans are concerned about—access to the medical treatment of their choice. The American people are growing frustrated with the limited number of therapies and treatments available to them today. In this day of advanced technology, there are hundreds of therapies and treatments for ailments such as allergies, lyme disease, cancer, and AIDS that are not offered to the American people.

At the same time, I have heard from health care providers frustrated that they cannot offer some therapies which they believe can provide their patients with real benefits. They feel as if their hands are tied when standard treatments fail, and they are unable to offer alternative choices.

This is an issue that has personally affected several of our colleagues in the Congress. I know my good friend from Iowa, Senator Tom Harkin suffered from debilitating allergies and found relief with a simple dietary supplement of bee pollen after trying many over-the-counter and prescription antihistamine drugs. Many of us also know the story of our distinguished former colleague, the Honorable Berkley Bedell, who retired from the Congress due to Lyme disease. He had tried many approved antibiotic therapies, spent thousands of dollars, and got little result. Upon learning of an innovative therapy involving the use of specially processed whey derived from bovine colostrum, Berkley Bedell found not only relief from his symptoms but an apparent cure. I am pleased that he is here with us today and that we will have the opportunity to hear his story and receive his counsel.

I know this issue will require us to deliberate carefully on how we can set up a procedures that allow consumers access to the therapies and treatments of their choice and that also recognize that government has an important role in protecting the consumer. We will develop that aspect in this legislation. Safety is a paramount concern. At the same time, however, I cannot stand by and let our government deny its citizens the freedom to make their own informed choices about treatments and providers.

I look forward to hearing from the various groups and individuals who have experience with this issue. I believe that this legislation is the first step to giving the American people what they want, which is access to medical treatments.

Mr. Chairman, I support Senators Daschle and Harkin in their efforts to restore freedom of choice to the American people on this health care issue. There are few decisions, after all, more personal than health care decisions. I am prepared to support this legislation, and I would encourage each member of this committee to give our citizens access to a broader range of medical treatments by supporting it as well.

Senator HATCH. Let me just ask you this, Dr. Burlington and Ms. Pendergast. You say that it was back in 1976-78, when this first came to the attention of the FDA. I can understand that it may have been looked upon a little askance then, but in the intervening years it hasn't been.

How long has it been since the FDA has taken this matter seriously?

How many years has that been? Approximately what kinds of resources are being used, and just what is happening with regard to the claims of people that this is an efficacious treatment? You don't have to give us exact figures; just give us some ball park numbers.

Dr. BURLINGTON. Senator, in the 16 years since we originally considered this at the panel, I know that there has been additional effort on it. I know that a substantial part of that has taken place in the last 2 years. The cost and the number of people involved are information that I will have to obtain from staff and supply later, if I may. I don't have that readily available.

The issue here really is, I believe, as Ms. Pendergast said, the systematic collection and submission of data. We are prepared fully to look at data from overseas. We are prepared fully to look at acupuncture as we would look at any other device. The fact that it may have at times had an alternative therapy label doesn't influence the way we approach the subject, but we need to make a decision based on the data that is available.

Senator HATCH. But it is all their obligation to come forward before they can use any of these therapies and prove that to you it is efficacious?

Dr. BURLINGTON. The current structure is that the individuals wishing to market the product need to marshall the data and bring that to the agency.

Senator HATCH. We have a number of witnesses here, and one of the most distinguished, of course, is our former colleague, the Honorable Berkley Bedell, who retired from Congress due to lyme disease. He had tried many proved antibiotic therapies, spent thousands of dollars and got little result. Upon learning of an innovative therapy involving the use of specially processed whey derived from bovine colostrum, Berkley Bedell found not only relief from his symptoms, but an apparent cure.

I am really pleased that he is here with us today, and one of the reasons I am sponsoring this bill is because of Berkley Bedell and others. I look forward to hearing his story. One of my worries and one of the constant complaints I get is that the FDA, instead of

being a facilitator to get good health care out there to the American people, is an inhibitor.

Now, I know you are constantly in that vise between approvals and nonapprovals, and people are pushing you when you have this very responsible job of trying to do what is right. On the other hand, a lot of us are very concerned that there isn't the progressive, forward look that will allow some of these alternative therapies the opportunity to compete with the more traditional therapies. This is especially true since a lot of people are finding these alternative therapies more therapeutic and more efficacious than some of the more traditional and accepted therapies.

So I really want to thank our colleagues here who have shown an interest in this—everybody here at this dais has shown a great interest in it. I also want to recognize Senator Harkin and Senator Daschle for leading out on this matter, and also Berkley Bedell. I have to go to the other Labor Committee hearing, but I am very interested in what happens here today. I am interested in reading this record and, of course, participating in resolving the issues which may impede this legislation. So I am going to help you, Senator Harkin, as much as I can.

Senator HARKIN. Well, we have worked very closely together in the past and I look forward to that close association in the future.

I want to yield to my colleagues, but I just want to follow up on the acupuncture issue and I just want to ask you one question. What is your position in the FDA today on someone in this country, a practitioner, using acupuncture needles? Is it legal or is it illegal? Is it approved or is it not approved? Is the use of acupuncture needles approved or not approved?

Senator HATCH. Could I add just one thing? One of the leading neurosurgeons in the world has indicated to me that he has recommended acupuncture as something that has really worked with a number of people and he believes in it. This fellow is a very practical, world-recognized neurosurgeon.

Senator HARKIN. Why is it so difficult to answer my question?

Dr. BURLINGTON. Mr. Chairman, the regulation of the practice of medicine and allied health professions is, of course, the province of the States, and also under the constraints of the institutions in which such practice takes place. The agency tries to stay out of that. We ordinarily don't reach into the question of whether a practitioner applying acupuncture is acting in concert with the laws in the jurisdiction in which they are working or not.

In terms of the question of whether the needles used in acupuncture and various other devices used in acupuncture may be legally distributed, the agency has accepted that there is a widespread use of them for investigational purposes. We look in terms of the approval for marketing in terms of the specific claim structure that goes with the needles; that is, whether they are intended to be for relief of pain or for various other uses. Unfortunately, I don't have with me today all the information on that, but I can certainly again get the information on the status of such applications for you.

Senator HARKIN. What if the needles are shipped in interstate commerce?

Ms. PENDERGAST. They may be shipped in interstate commerce if they don't make claims that these needles cure pain; these nee-

dles, you know, make you sleep during surgery. If they are simply shipped as needles and if a practitioner uses them in the course of his or her medical practice, that is a question for State law. That is a question of medical malpractice, of whether they have privileges at the hospital to use such acupuncture needles, and the like. That isn't something that the FDA rules on. That is outside of our jurisdiction.

Senator HATCH. Can they say if they are used for acupuncture or not on the label if they ship them in interstate commerce?

Ms. PENDERGAST. We need our lawyers.

Senator HARKIN. Well, someone is the head of the devices here.

Ms. PENDERGAST. No, it would probably not be legal. That would probably be considered making a claim.

Senator HATCH. In other words, you would consider if they ship the—they are not necessarily needles; they may be plastic needles, I guess you would call them. They may not be metal needles, but if they ship them in commerce as acupuncture needles to be used in alternative therapies, you are saying that is illegal?

Ms. PENDERGAST. Again, it goes to the question of at the present time acupuncture needles require pre-market approval of the FDA before they can be sold as acupuncture needles. So if a company wanted to engage in widespread marketing, they would be violating the prohibition against widespread marketing of a device that hasn't been approved.

However, if the company is shipping the needles for investigational use by physicians in an effort to obtain the information necessary to obtain marketing approval, that is acceptable under the law. So, I mean it is a question of intent and if the company is attempting to comport itself with the law or simply ignoring it.

Senator HATCH. May I ask one other question, Mr. Chairman?

Senator HARKIN. Yes.

Senator HATCH. Could I just ask what is the average time of approval for medical devices at FDA currently?

Dr. BURLINGTON. For abbreviated applications for products which are substantially equivalent to those previously legally marketed, we are running at about 170 days of FDA time.

Senator HATCH. 170 days?

Dr. BURLINGTON. Yes, sir.

Senator HATCH. Almost 6 months?

Dr. BURLINGTON. That is correct.

Senator HARKIN. You understand what he said. That is for things that are substantially like those that have already been legal in the past.

Senator HATCH. Sure. Now, what about those like acupuncture needles?

Dr. BURLINGTON. Those for new uses, those which represent new technologies that raise new questions of safety and efficacy take us considerably longer. We are currently operating around 2 years of FDA time. Total time may well exceed that. These are not time frames that we are proud of. They are time frames we are working very vigorously to reduce, and have made substantial progress against the number of applications in backlog over the last year.

Senator HATCH. Well, that is unacceptable.

Dr. BURLINGTON. The agency certainly agrees with you, Senator.

Senator HARKIN. Thank you. Before I yield, I will just make one statement here. Every time I have been in a hearing or I read something about the FDA—and I have a lot of respect for the FDA.

Senator HATCH. So do I.

Senator HARKIN. We are not trying to do away with FDA at all. We are just trying to broaden this thing and open it up a little bit and expedite things a little bit here. But I always hear the example of thalidomide. Please, that car is about out of gas. [Laughter.]

Shall we talk about silicone breast implants, shall we talk about halcyon [sic], shall we talk about pacemakers, all of which have caused innumerable harm, suffering, death, illness, and all of which are approved by FDA? So, you know, we can balance this out?

Ms. PENDERGAST. Senator, we take your criticism about thalidomide. We use it because it is an example everyone understands. There are other examples of drugs that also caused harm, were approved in Europe, were approved elsewhere, and that FDA caught and didn't put on the American market.

But the examples you give, silicone breast implants—they are in the same position as acupuncture. They were never approved by the FDA. In 1976 when the FDA first got jurisdiction over those silicone breast implants, the FDA put those also into class III and said you needed pre-marketing approval application. So, that is an example——

Senator HARKIN. Was haldone approved by the FDA?

Ms. PENDERGAST. Is that halcyon?

Senator HARKIN. Halcyon; I am sorry. Halcyon, halcyon.

Ms. PENDERGAST. Yes, halcyon was approved by the FDA, and we have recently taken a hard look at all the scientific data. We have worked closely with our colleagues in England and in Germany and in other countries to reassess that drug, and we do believe that, used for short periods, 10 days at a time, it is, in fact, a safe and effective drug for its labeled indication. Not the way all doctors were prescribing it to all patients, but as it is labeled we believe it is a safe and effective drug.

Senator HARKIN. Senator Daschle?

Senator DASCHLE. Thank you, Mr. Chairman. I have appreciated the questions and some of the answers provided by FDA. I must say, Ms. Pendergast, that I am somewhat disappointed, in your testimony, not because you are critical of the bill, but because you really don't offer any alternatives or any constructive solutions. I wish your testimony would have been more forthcoming in terms of what we can do to address the problem, rather than just to be so roundly critical of the solution that we propose.

It is ironic to me that, in this country which justifiably boasts of its freedoms, we can be so constrained when it comes to this particular issue. If we would do to speech what we have done to access to medical treatments, most of us would probably be in jail today.

We often judge our freedom and the quality of our health care, in particular, by the number of people who come to this country. We have thousands of Haitians who are coming to this country to seek freedom today. We have thousands of people who come to this country to seek medical treatment because they believe it is exceptional. Yet, we have thousands of Americans who seek care in other

countries simply because they have the freedom to do so there, and that, to me, is the irony. In this country which boasts of freedom, boasts of opportunity, we deny people fundamental opportunity day after day in something as consequential as their health.

It seems to me that if indeed you are interested in addressing that problem, we would see more action and less rhetoric. I don't see the action, and when I hear criticism of our bill, which proposes action, with no alternative, then, frankly, I am not very impressed.

I would hope we could work together. I would hope we could come up with some constructive solutions, but I don't see them, and I frankly am disappointed that in this administration, in particular, couldn't take a positive attitude, toward this particular challenge.

We aren't trying to change the approval process. That is not what we are all about here. What I am concerned about is whether or not we are going to give consumers choice; choice that allows them, with their eyes open, to make fundamental decisions about their own future and their own health. Our system doesn't allow that today. The acupuncture questions that have been asked this morning demonstrate that point unequivocally.

The issues that Senator Harkin has raised demonstrate that even FDA approval is not a guarantee of safety. So let us recognize that the government cannot be the end-all when it comes to the personal, very extraordinarily difficult decisions that human beings must make daily about their lives.

Could you tell me this morning what percentage of those products approved over the last 5 years have come from small companies or individuals?

Ms. PENDERGAST. Senator, we will have to get the information on that specific point.

Senator DASCHLE. Well, just give me a rough guess.

Ms. PENDERGAST. I think it depends. For drugs, it is probably a smaller percentage than devices. Many devices are developed by an entrepreneurial physician or health care practitioner. It is an industry with very smaller companies. Drugs are harder. We do have some notable success stories, recent success stories. For example——

Senator DASCHLE. I would like to hear the success stories, but in what limited time I have, give me some appreciation—you have been in this business long enough to know—of the ratio of big to small in the approval process, or the percentage. I will take it either way.

Ms. PENDERGAST. I am certain it is a small percentage. I don't know the figures.

Senator DASCHLE. What is it?

Ms. PENDERGAST. I do not know at this time.

Senator DASCHLE. Is it 1 in 10, 1 in 20, 1 in 1,000?

Ms. PENDERGAST. I am sorry, Senator; I don't know.

Senator DASCHLE. You have no idea? Somebody must.

Dr. BURLINGTON. Senator, for devices, we do know that a substantial majority of new products entering the market are from what are traditionally defined as small businesses with less than 500 employees.

Senator DASCHLE. No. I am asking, under the process of approval to which new products are actually subject, what is the percentage of those products that are initiated and produced by very small companies?

Dr. BURLINGTON. We know, again, that a substantial fraction—I don't have the figures immediately available, but I think it is around 16 or 17 percent—are brought by companies with less than 20 employees, start-up operations, by and large, for devices.

Senator DASCHLE. We will just leave this for the record, but I would really like a breakdown if you could give it to me.

[The information referred to was not received at the time of printing.]

Senator DASCHLE. The point of the question is pretty obvious. We are in a position today where governmental entities seem to be, in essence, protecting the large corporate interests and not providing opportunity for small developers and producers to come forth with innovative new products. That is the issue. Because of our regulatory process, we have in effect become the protector of the large corporate developer rather than the protector of the consumer. That is what has happened. What we want to do is to do a better job of reconciling the dual goals of protecting consumers and assuring that they have many of the choices that are available to them in other countries but are denied in the United States. I don't think we have done that very well and, frankly, I think it would be very helpful if you could help us achieve that.

Ms. PENDERGAST. We appreciate your concern. We, too, recognize that, as Senator Simon mentioned and Senator Hatch mentioned, one of the structural problems is getting the ideas from the small entrepreneurial health care practitioner who has an idea, getting that idea through the scientific process, actually being able to do the studies. That is why we commend Senator Harkin for establishing the Office of Alternative Medicine at the NIH. We think that that is the kind of thing that will solve the problem of the widespread use, but there is no one company that can make the profit, no one company that can patent the product.

Anybody can sell whey. I mean, I spent most of my childhood on a dairy farm; I mean, you could just go get it. So, you know, I appreciate that concern, and that is why our orphan drugs program where we give small—it is the only place where the FDA is allowed to give grants—where we give grants to individual researchers to get them started with the new idea, but that is where we have to hand off the ball to other funding institutions that can then help pick up the ball.

We are limited by what our role is. Our role is not the entity that funds. Our role is the entity that reviews the research that was funded, and all we are saying is that we want to work with you, we want to help you develop a bill that gives access to promising therapy, but we want to help you develop a bill that gives access at the same time data is collected so that 5 or 10 years from now the people who are using, quote, "an alternative therapy" will get it into mainstream medicine and we will all benefit from it. If we don't collect effectiveness data, 5 or 10 years from now, unless some other country picks up the ball, we still won't know the answer.

You know, we all suffer from disease. We all have families. It matters to all of us. We are not trying to keep this from people. We are trying to get it structured in such a way that we can all benefit, and not just the lucky person who goes off and gets the therapy abroad.

Senator DASCHLE. There are a lot of witnesses and I don't want to prolong this, but let me just emphasize that we are not plowing new ground here. We should not be so egocentric as to think that we have to invent something that hasn't already been discovered. All we have to do is look at a myriad of other industrialized countries who have faced the very same questions and have come to a vast different conclusion about this freedom of choice issue.

I think it is fundamental to understand that there is no need to reinvent the wheel. There is no need to dramatically change the FDA approval process. We just need to be more sensitive to the challenges and the opportunities and the excitement that exists in the market today. Our government is behind the times when it comes to this realization. Other governments have recognized it earlier than we have, and I think it is time we do.

I realize we have a lot of witnesses, Mr. Chairman. Thank you for the time.

Senator HARKIN. Thank you very much, Senator Daschle.

Senator Simon?

Senator SIMON. Yes, and I may ask my friend, Berkley Bedell, to come up here and provide some additional information because I can't stay. I have got to go to another hearing.

If I can go to Berkley Bedell's situation where he had lyme disease—and he and I and Dr. Kessler had dinner together one evening and had a chance for a discussion. If the physician who gave him the whey were to send out whey or send out a letter saying whey may solve your lyme disease, is that legal now?

Ms. PENDERGAST. If a physician gives Congressman Bedell whey, that is legal. It is not something the FDA has jurisdiction over. Again, it is a question of State law. I see very little likelihood that it would be a problem under State law.

Senator SIMON. Berkley Bedell, would you mind joining the panel up here, if I may, Mr. Chairman? I am sorry to do this, but I am not going to be here when——

Senator HARKIN. It is highly unusual, but we will welcome Berkley to the witness table. Certainly, I understand your time constraints, and since this involves his own particular treatment, I think it is advisable that he join us at the table.

Senator SIMON. Is what Commissioner Pendergast said correct?

Mr. BEDELL. The problem is that the whey came from a producer from another State, and that producer does not have the money to go through the multimillion-dollar process to get the FDA approval in order to be able to ship that whey, or sell that whey to any other producer. So it is completely illegal, it is my understanding—and if I am wrong, Ms. Pendergast, you need to correct me, but my understanding is that nobody can produce whey to try to treat lyme disease, whether claims are made for it or not, and ship it to another doctor for them to use in treating lyme disease. If that is wrong, I have got an awful lot of people that would be tremendously anxious to be able to avail themselves of that treatment who

are just suffering terribly from lyme disease and cannot be treated with the treatment which I obtained. Am I correct or wrong?

Senator SIMON. Commissioner?

Ms. PENDERGAST. I do not think that it is exactly correct. If a producer wants to produce whey and sell that whey in drug stores, health food stores, whatever, and sell the whey, that is perfectly legal.

Mr. BEDELL. No, no. To furnish it to a doctor to treat patients for lyme disease—can they do that?

Senator SIMON. And if he doesn't claim that it will cure, but it may cure.

Senator HATCH. Make the claim, in other words.

Ms. PENDERGAST. The courts have held that "this may cure" is the equivalent of "this cures." That is considered a claim. The question is one of labeling. The law says you can't ship something in interstate commerce for a specific medical use and claim that it will do a cure unless it has received the FDA's approval.

However, if you don't have those claims, then you can sell it, and if a doctor wants to use it or if a patient wants to use it, that is the practice of medicine and that is not our concern. If you go to any health food store in this country, you will find many products that people in this country use. They use lecithin, they use high-dose vitamins, they use things. That is all right. That is the practice of medicine. That is individual freedom.

It only goes to when a company promotes its product and says this will cure. That is the point where we step in and say, the law says you have to prove it before you claim it, where is your proof?

Senator SIMON. But if that physician sends it and says, this may cure, what about that?

Ms. PENDERGAST. That is the physician-patient relationship. That is the practice of medicine and that is not the business of the Food and Drug Administration.

Mr. BEDELL. No, no, that is not his question. His question is can that company ship that and say that this may cure lyme disease?

Senator HATCH. Or can the physician make the claim and tell other physicians that this has really helped with lyme disease? Your answer is no.

Ms. PENDERGAST. A physician can. If a physician wants to——

Senator HATCH. With other physicians and across interstate lines?

Ms. PENDERGAST. No. If the physician wants to write a journal article, give a speech, go to a seminar and present his or her views on the therapeutic benefits of whey, there is freedom of speech in this country. Physicians are permitted to do that. There is nothing wrong with that.

Senator HATCH. What if a physician says this manufacturer of whey manufactures a high quality of whey that may have beneficial effects on lyme disease? He can't make that claim?

Ms. PENDERGAST. He still can make the claim. As long as the physician is not basically an employee of the company and standing in the shoes of the company, the physician may still say that. It is when the corporation that is selling the product——

Senator HATCH. We just found a way around the dietary supplement industry problem, haven't we?

Ms. PENDERGAST. Well, that is legal now. It is a question of the company. When the company markets the product, when the company makes the profits off the product, that is when the FDA says the law says prove it. If a doctor thinks that drinking milk cures a disease and says drink milk or eat whey or eat bee pollen, or whatever, that is okay.

Senator HATCH. But the company could not use under current law that physician's statement or claim?

Ms. PENDERGAST. That is correct because then the company is just basically taking the doctor's statement.

Senator HATCH. What if the physician makes a royalty or makes a profit from it as well?

Ms. PENDERGAST. If the physician is part of the corporation——

Senator HATCH. Then that is it for him; he can't make a claim?

Ms. PENDERGAST. Then he is standing in the shoes of the corporation. You have to look at the corporation.

Senator HARKIN. Let me just see if I can crystalize this again. A farmer in Wisconsin produces this whey.

Ms. PENDERGAST. Right.

Senator HARKIN. A doctor in Iowa wants to treat someone in Iowa with that whey for lyme disease. He goes up to Wisconsin and he says, I want you to ship me this stuff and I want to use it, and he ships it into Iowa to use and he tells the patient, look, I don't know if this will help you or not, but it helped Berkley Bedell and it has helped other people; I don't know if it will help you; I don't think it will hurt you, but I think it might help you, and would you be willing to try it? They say yes.

Are you telling me that the FDA will take no action against the shipment of that from one State to another?

Ms. PENDERGAST. That is right. If that company is not claiming that whey does something, it is shipping whey. It is not a concern of the FDA. We only care about it when the company makes claims that the company can't back up. That doctor can freely do that without any problem whatsoever from the Food and Drug Administration.

Senator HARKIN. Well, Mr. Bedell?

Mr. BEDELL. We may not need this legislation. [Laughter.]

If indeed the testimony of the FDA is that anybody can make any medicine they wish to and ship it in interstate commerce and anybody can use that medicine without going through the FDA approval process, that is all we want, if that is indeed your attitude.

Senator SIMON. But she is not quite saying that. What she is saying is this may help. If there is a claim that this will help, then the FDA moves in and stops it, and I think properly. If the whey is sent and it says this may help you, then my understanding is the FDA, if I hear the testimony correctly, does not move in. Is that correct?

Senator DECONCINI. No, no.

Ms. PENDERGAST. Whether it says this will help or it may help, it doesn't matter. We would move in. It is the claim, it is the claim. If whey is sold as whey without any claim by the company—if the company making the money off the whey makes no claims about it, doesn't try and market it as a cure-all, just sells it as whey, and a doctor, through reading scientific journals, going to meetings or

conventions, or whatever, learns of the use of whey and chooses to administer it to a patient, that is legal. That is the practice of medicine.

Now, obviously, if whey—it is not, but were it to be highly toxic and it harmed the patient, the doctor might get in trouble with the State licensing boards, or medical malpractice action could be taken, but that is not us. That is not an issue we care about. Our Act steps in when companies make claims that they can't support with scientific evidence, and that is where our law kicks in.

Senator DECONCINI. Could the Senator yield?

Senator SIMON. Yes.

Senator DECONCINI. It seems to me that the hypothetical that the Senator from Iowa gave is so isolated. In order to get the use of whey, or for acupuncture needles, people have to be told by other patients, hey, this is great, use it, and that is how acupuncture is passed on and I am a perfect example of one who goes to an acupuncturist. He does not represent, nor do these needles that he gets from China represent and advertise that these needles are going to stop the pain in your back, but the word of mouth is what has done it and the continuing referral.

Now, the needles have not been approved, so if you had a big effort to sell these needles to acupuncturists, then they would be subject to it. So I see the point here, but the reality is that I don't think Mr. Bedell and his people that need the whey have any information of it. So where do they go? They go to their doctor and the doctor says, I don't know anything about it, and so it has to come from the patient instead of from the medical side.

That is what Tom Daschle points out, that we don't have a medical system that looks to this choice, to the consumer's best interest. They are confined from what they learned in medical school.

Senator HARKIN. That is a very good point, very good.

Senator SIMON. Then if I may ask the Commissioner, then, how do we structure something so that we can test a product that no one is going to make a profit on?

Ms. PENDERGAST. That is a difficult question. The Government obviously plays a role in that. I think that our grant program plays a role. It is the same question we have over vitamins. How do you organize large-scale trials of vitamins when there are 300 or 400 vitamin companies and vitamins aren't patentable?

So if one company spends the money—and, by the way, it is not millions. It can be much smaller sums of money, but whenever one company does the research it then benefits all, and I think we have to tried to encourage industry to pool their resources to have consortiums, to have all the, let's say, vitamin companies join into a pool to do research. Obviously, the Office of Alternative Medicine is a place we all look to for this kind of research. Some of the other NIH institutes are funding dietary supplement trials.

I think the research is the hard part because I think that we all have the same goal. You want choice, but you want informed choice. You can't have informed choice unless there have been some studies, and how do we get those studies done?

Senator SIMON. I am unfortunately going to have to get to another meeting. We sound like we are pouncing on you here, and we don't want to convey that we are not appreciative of the superb

work done by the FDA. But I think there is also a feeling that we are closing access to a lot of people to some things they ought to have access to, and somehow, whether it is this legislation or whatever it is, we have to open up that access a little more.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Simon.

Senator DeConcini?

Senator DECONCINI. I will be very quick. Is the FDA prohibited from its own initiative on a product that is not being promoted for profit?

Ms. PENDERGAST. We do not have statutory authority to conduct the research and to gather the evidence.

Senator DECONCINI. So you can't go out and do your own investigation unless someone has brought you the product. Is that correct?

Ms. PENDERGAST. With one exception. The Center for Biologics, which has also authority under the Public Health Service Act, can do research and, in fact, they do. Some of the vaccines in use in this country today, we helped develop.

Senator DECONCINI. The reason I asked the question is, take acupuncture. Knowing how the feeling of just this committee is and the public is on it, are you prohibited from going out and finding what needles are used in acupuncture and then doing some research on them, or making a grant to someone to do some research on them?

Now, the institute is doing that under what the Senator established on alternative medicines, and I know it is going on now, but I mean can you do that to expedite it when you know that there is really some interest in this one?

Ms. PENDERGAST. A very small amount of our appropriation permits us to do research. It is principally in the orphan products program, but orphan drugs are defined as—these are conditions that fewer than 200,000 people have, so if it was acupuncture and pain, they may not be eligible. But we are basically——

Senator DECONCINI. Well, if you wanted to really move this along, you would feel that you could not go out and solicit from acupuncturists needles that they use and then do some tests on them on your own?

Ms. PENDERGAST. We have—and I will let Bruce add—we have held seminars and we are trying to get people to give us data and to seek——

Senator DECONCINI. But you are waiting for them to come forward in the process of promoting the sale of those needles?

Ms. PENDERGAST. Yes. I mean, we turn to the Office of Alternative Medicine for this. It is sort of what role our agency plays.

Bruce?

Dr. BURLINGTON. We are able on our own initiative to have some limited ability to go look at the needles, do testing and see what their physical characteristics are. We have that level of laboratory support.

Senator DECONCINI. Have you done it, then? Have you done it?

Dr. BURLINGTON. I don't know the extent to which that has gone on, but we will have to find out.

Senator DECONCINI. Would you please do it for us?

Dr. BURLINGTON. Yes, Senator. In terms of looking at clinical data to support the application for reclassification of acupuncture needles, the agency simply doesn't have the structure and resources to generate that data on its own. Rather, we work with the practicing community, attempting to help them organize the data, and that was the purpose of our recent seminar that we just spoke of.

Senator DECONCINI. Mr. Chairman, thank you. I won't belabor the point. Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much, Senator DeConcini.

I know Senator Daschle had a follow-up question.

Senator DASCHLE. I didn't want to interject every time I have a concern, but just in closing, there has been a lot of skating through semantics here and I think it is very important, as meaningful as these terms and words are, that we call attention to a couple of facts.

No. 1, the statement was made that a person can't make a claim if there is no scientific evidence to back it up. We agree and that point is crucial to our bill. We need to move beyond that point, however, to an exploration of alternative treatments and how we can facilitate their entry into the market.

No. 2, I think there is a substantial difference between stating that a treatment will do something and stating that it could or may do something. It is the FDA's position that "may" and "can" are one and the same, and I really think that we have got to be very careful about that. There is a substantial difference, and therein lies the freedom of choice issue.

If we really want to help consumers, we must be willing to give them more latitude and more flexibility and discretion, especially when we aren't willing to define our terms more carefully regarding things as consequential as the words "may" and "can."

With that, Mr. Chairman, I thank you and I thank our witnesses.

Senator HARKIN. Thank you, Senator Daschle. I just wanted to again just close on this. We have to move on, but——

Mr. BEDELL. I want to say I am glad to be part of the FDA panel, Mr. Chairman. [Laughter.]

Ms. PENDERGAST. We welcome your participation.

Senator HARKIN. Ms. Pendergast, in your written testimony you say that, ". . . 80 percent of the drugs tested through careful and scientific methods never make it past the early safety and effectiveness studies in Phase 2." You say, "Therefore, under this bill, 80 percent of the medical treatments either will not work or will be harmful." That is a pretty blatant statement of fact that I don't think can be supported. That is more speculation than it is fact. I would point that out. It is based upon your record. I would just say that you would speculate that based upon your past record, perhaps as high as 80 percent would prove harmful.

Ms. PENDERGAST. I take your point. I think this may have been chewed a bit in editing. What we were saying is if history is a guide, then approximately 80 percent will also not work, either won't work or will be toxic. I take your point.

Senator HARKIN. I appreciate that. Again, I am a little concerned about another aspect, perhaps something that you alluded to that

I want to correct the record on here and want to make it as clear as I can. Does the FDA have enforcement power?

Ms. PENDERGAST. Yes, we do.

Senator HARKIN. The FDA does have the power, for example, to bring sanctions against a manufacturer or practitioner who utilizes a device or a therapy that has not been approved by the FDA. Does the FDA have enforcement powers?

Ms. PENDERGAST. The Food and Drug Administration has enforcement powers against companies who violate what is called a prohibited act in our statute, and shipping products that have to receive FDA approval, but have not received such approval is a prohibited act. So if a company were doing such a thing, we could go after the company. The opportunities——

Senator HARKIN. Excuse me. Let me interject here. I am sorry to cut you off. If a practitioner——

Ms. PENDERGAST. It is a much more complicated question because of the practice of medicine, and almost, but not precisely all of the behaviors of a practitioner fall outside of the Federal Food, Drug, and Cosmetic Act. There are some circumstances, particularly in the device area, where if a physician—and we had the situation about a year ago; physicians were injecting reagent-grade silicone into people's faces and causing them disfigurement.

We did in, that circumstance, because of the grievous bodily harm, go after some of the physicians and tell them to stop. But the vast majority of the time, it is not the practitioner that we look at; it is the company that is selling the product.

Senator HARKIN. Have there not been instances and cases where cases have been brought by the Food and Drug Administration against licensed medical practitioners who were using devices or therapies not approved by the FDA for which no harm was claimed by any patients that they served, and yet the Food and Drug Administration took action against such practitioners?

Ms. PENDERGAST. I cannot think of a case where that particular fact pattern exists. If you have a particular case in mind, we would like to go over with you the reasons for the bringing of the case.

Senator HARKIN. Well, you kind of alluded to one in your written testimony that I am somewhat aware of, although it is not the specific case because I didn't know about Florida, but I do know of a medical practitioner that was using ozone treatments for patients. To the best of my knowledge—and, again, I can't say this authoritatively, but to the best of my knowledge and information, no patients had complained or filed any charges or anything like that that they had been harmed in any way by these treatments. Yet, the Food and Drug Administration came in and shut this operation down. I can get you the information on that. I do have quite a bit of it.

Ms. PENDERGAST. Mr. Michaels? We could perhaps discuss that case.

Mr. MICHAELS. Mr. Chairman, I think the distinction may be between whether any of the particular treated patients complained, as opposed to the risks that they may, in fact, have been subjected to. Ozone is not an innocuous material and we have been taking action against purveyors of ozone generators in a number of different cases.

So, as a general matter, we have concluded that without evidence to show that these devices are, for the particular claims being made, safe, effective, and reliable—where the opportunities have arisen because of our belief of the risk presented to those patients, we have taken action.

Senator HARKIN. Doesn't what you just said to me contradict what you earlier said about the practitioner in terms of dealing with a patient, that you would take no action against a medical practitioner for using a device or a therapy? It seems to me this contradicts what you just said earlier.

Mr. MICHAELS. Mr. Chairman, not knowing the specific case, physician involvement or not, I was trying to draw the distinction between patients complaining or not complaining. If patients don't complain, or those exposed to the device don't complain, one should not conclude that they are not being harmed. The reality is ozone is not an innocuous material, and that is why the agency has taken action against ozone generators.

I am sorry, sir. I don't want to prolong the dialogue here, but I wanted to make that distinction. I am not addressing your point about physicians' involvement in the particular thing. We would have to look at the particular case.

Senator HARKIN. Well, again, are you aware that ozone treatments and ozone generators are used extensively in Germany?

Mr. MICHAELS. Yes, sir.

Senator HARKIN. And are, in fact, an approved practice in Germany and are, in fact, paid for through the government health insurance program. I think we have someone from Germany testifying. I will ask him that later today. So, again, I mean, you know, Germans aren't exactly neolithic people. [Laughter.]

I mean, they are pretty advanced, and yet nothing has been done in this country to in any way look at that and try to enable people here to have ozone treatments. In fact, the machine in question that I was aware of, anyway—again, I haven't seen it, I haven't laid hands on it—I was told, came from Germany, was approved in Germany, and was being used here. The patients had not complained, and yet the FDA found out that this practitioner had been utilizing ozone treatments and summarily shut him down. They took his records, took everything away from him.

Mr. MICHAELS. To go back to the root issue, Senator, I agree with you that therein lies one of the fundamental dilemmas that we are all trying to grapple with, getting the information in order to make good judgments about these things.

Senator HARKIN. Well, then what is the difference between that and the practitioner who gives whey to Berkley Bedell? I mean, no one complained, but it wasn't approved and it is not approved by you. What is to keep you from coming in and saying it is not approved and we will do the same to you as we did to this person with ozone?

Mr. MICHAELS. Again, sir, I think we would have to look at the specific case to which you are referring to adequately respond to your question. I don't wish to duck the issue, but I am sorry. I cannot fully respond to your question without knowing the case.

Senator HARKIN. Well, I will get the case.

Ms. PENDERGAST. And we will discuss this with you further. Two distinctions that come to mind immediately are, first, that whey is otherwise a food and people can lawfully sell food in this country without prior approval. Second, whey is not known to be dangerous and we——

Senator HARKIN. But just a moment. This is not just whey. Berkley can correct me if I am wrong, but if I am not mistaken, what they have done is they have injected a pregnant cow with contaminated blood, or blood from the person who has lyme disease that would carry that virus, or whatever it is. They inject in the cow and then the first milk from that cow was taken, which may contain some elements other than just the milk that the cow gives. So this isn't just pure whey, okay? So let's get that clear. Something has been done to that cow beforehand.

So, now, would you like to revise your answer? No? Then how do you know it is not harmful? How do you know that it is not harmful to people? You told me it wasn't, but how do you know it is not?

Ms. PENDERGAST. Obviously, we were under the impression you were referring to whey. We would like to learn more about the situation from Congressman Berkley Bedell because we were under the perhaps misapprehension that it was whey. I am not sure that what you have told us would change our minds about the potential danger that exists with this product. We would obviously have to learn more.

Senator HARKIN. Well, again, I still don't understand why that would be different than the ozone. I just can't see that in my mind why one would be shut down and the other one would be allowed to continue. Perhaps we have to figure this out further?

Ms. PENDERGAST. I mean, oftentimes, you have to look at the claims that are being made by the manufacturer of the ozone generator, and the ozone generator, if the claims made are unsubstantiated and it is sold in contravention of the law, then sometimes we take action against the machine and just try and stop the use of the machine. If a physician continues to use the machine, we may ask the physician to discontinue use of that illegal machine.

Senator HARKIN. I am sorry I can't remember. I will find out and I will get that to you. I would like to take a longer look at it. Well, obviously, this is a fairly complicated issue. As I was listening, I was trying to read through your problems with the bill, and I must admit that you do make some good points in there in terms of no requirement for the health care practitioner to provide the information to the patient in writing. These are modifications to the bill that we can make, and I appreciate that. That is a very constructive criticism to the bill.

Again, on how people are informed and what penalties might apply, you say there is no penalty for health care practitioners if they do not report harm associated with treatments, and no method for any entity to enforce the requirement. Well, we should look at that. I think that is a constructive criticism and we will look at that.

So there are some things, I think, that we might work together on in this, but I do diverge from you when you say that there is no necessity for this type of legislation. The public out there is saying that there is a necessity for it. As I have pointed out, the New

England Journal of Medicine reported that 1 out of 3—and much of this is underground. It is happening underground, and because it is underground there is a blanket of fear among medical practitioners in this country today that they cannot do that, for fear that the FDA will shut them down or will report them to the medical authorities, who then may take action against them, because of this blanket of fear.

Otherwise, conscionable, well-meaning practitioners licensed by States are doing things underground and not enough information is getting out there. What we are trying to do with this legislation is bring it out from the underground, make it legal, give people the information that they need, and let consumers—as Senator Daschle so eloquently said earlier, give them a broader choice, but it must be informed. They must be informed, and adequately informed, of what is going on that the FDA has not, in fact, proven this to be safe and effective, and let the consumer then make some choices on that.

Again, I agree with you that people who are ill sometimes can be preyed upon by people who are unconscionable and who only want to make a quick buck. We must, of course, guard against that because I know when people are sick they reach out in desperation sometimes for a quick cure or something like that and they can be subject to that kind of an individual who wants to prey upon them.

We do have to strike a balance. I think the scales are tipped a little bit too far one way right now, and that is why we set up the Office of Alternative Medicine and that is why I believe this legislation—perhaps it needs some work on it and we need to make some changes on it, but I believe we need to tip the scales back a little bit more and that we have to be more open-minded as to what other countries are doing, what other cultures have found out, and begin to let those new procedures and processes be adapted and be used in this country.

Perhaps by letting those be used in a more extensive manner, we may find that maybe we don't have a silver bullet that cures all cancers, but we may find some processes and some procedures that may help some people in certain individual cases. That is why I think this legislation, perhaps with needed changes, is vital for this country.

Ms. PENDERGAST. We would look forward to working with you on this legislation.

Senator HARKIN. Well, we will work with you. Thank you very much for being here. I appreciate it.

Ms. PENDERGAST. Thank you.

[The prepared statement of Ms. Pendergast may be found in the appendix.]

Senator HARKIN. We will call panel number two: Michaela Odone, Vernon Morin, Berkley Bedell, Spencer Cox, Bob Carolla, and Alexander Schauss.

I know the FDA people—I am sure you have tight schedules and you have to leave. Is there anyone that you have from the FDA that you will leave here to listen to the testimony?

Ms. PENDERGAST. Yes, Senator. We will have someone from the Office of Legislative Affairs here.

Senator HARKIN. OK, fine. You don't have to stay, but if you have someone here from FDA to listen to this testimony and take down—there may be new things that come up that I was not aware of.

Ms. PENDERGAST. Absolutely. We will be here taking copious notes.

Senator HARKIN. OK, thank you.

Again, I thank you all for being here today, some of you coming from a great distance and some of you I have had the privilege of meeting and associating with before. Obviously, I join with my colleagues in the accolades for Congressman Berkley Bedell. It has been said before that he was one of the main reasons why we are having this hearing and why we have developed this legislation.

I might also reach back a few years and say he is one of the main reasons we have the Office of Alternative Medicine at NIH, too, and I appreciate all of his support and his encouragement over the years for me, in particular, and for really getting my thinking more opened up on this whole area over the past several years. I publicly thank you for that, Berkley. Of course, Mr. Morin and I were on a television show together earlier this morning. Mr. Schauss and I have talked in the past.

I welcome you here. Again, you have heard the extensive testimony and question-and-answer with the Food and Drug Administration. We have copies of all your testimonies. They will be made a part of the record in their entirety. Again, I would just say that some of the best testimony, I think, that we get here is when people just speak from their hearts and their minds about their own personal situations and what has happened. Of course, if you have suggestions on the legislation, we want that, also.

So, please tell us in as short a span of time as possible what you really want us to take away from this hearing, and I would certainly appreciate that kind of brevity so that we might engage more in a question-and-answer session, as we did with the Food and Drug Administration.

I will start first, as I called them up, with Michaela Odone from Fairfax, VA. Of course, we all know you. Even though we don't know you personally, we know you and we know of your story, obviously, through the movie. Again, I just thank you for being a very courageous leader in the area of alternative medicine and for being so forthright to do all of the things that you have done in the last several years. You have given us a lot of encouragement. I welcome you here, and please proceed as you so desire.

STATEMENTS OF MICHAELA ODONE, FAIRFAX, VA; VERNON MORIN, GREENFIELD, NJ; BERKLEY BEDELL, SPIRIT LAKE, IA; SPENCER COX, PUBLIC AFFAIRS ASSOCIATE, COMMUNITY RESEARCH INITIATIVE ON AIDS, NEW YORK, NY; ROBERT J. CAROLLA, LEGISLATIVE COUNSEL, CONSUMERS UNION, WASHINGTON, DC; ALEXANDER G. SCHAUSS, EXECUTIVE DIRECTOR, CITIZENS FOR HEALTH, TACOMA, WA; AND DR. JOAN D. PRIESTLEY, EXECUTIVE VICE PRESIDENT FOR GOVERNMENT AFFAIRS, CITIZENS FOR HEALTH

Ms. ODONE. My name is Michaela Murphy Odone. I am deeply honored to have been invited to testify before this august commit-

tee. I am even more evermore honored to be the mother of Lorenzo Michael Murphy Odone. I am humbled to be here in his name, on his behalf, and on that of his small and fragile friends with ALD, on the very day that the U.S. Senate contemplates broadening access to medical treatments for degenerative diseases.

Childhood cerebral adrenoleukodystrophy is the steamroller of degenerative diseases. It maims, it mutes, it flattens previously healthy little boys along its sinister path within months of symptom onset, and until the development of Lorenzo's Oil, no break existed, no hope at all of heading off those symptoms before they raced on relentlessly to death.

Some of you may know the story of Lorenzo's Oil. Oddly enough, it is not a story about an alternative therapy. It is, rather, the story of a therapy for which in 1984 there was no alternative, and it is clearly the story of a desperate but methodical race to find an alternative to death, death within 2 years, the maximum life span meted out at the time by the official body of medical knowledge about ALD.

There is a saying that nothing focuses the mind like the knowledge that you will be hung at dawn. My husband, Augusto, and I beg to differ. There is nothing that focuses your mind, galvanizes your energy, and greases your roller skates quite like the knowledge that your child is sentenced to die at some grotesquely premature dawn.

What we did to invent Lorenzo's Oil is described in the January 5, 1989, issue of the Journal of Pediatric Neurosciences, which I have respectfully submitted for inclusion in the Congressional record. It is less technically described in the words of New Jersey science teacher Eileen Franklin commenting on the film: "It was a thrill to see the scientific method applied in the Odone's search to find a treatment for ALD. Not only was the importance of the scientific method demonstrated, but the point was made that professional scientists and physicians hold no monopoly on its implementation. It is there for all of us to employ."

Ms. Franklin's students are learning at a tender, unthreatened age what all of us here present have learned the hard way. As science sheds light, so too must its practitioners and its regulators be open to receiving light. Our letter to the editor of the New England Journal of Medicine of June 30 this year, which I have also appended to this testimony, summarizes what we now know after 7 years about Lorenzo's Oil that for the first time in medical history it eliminates the toxic fatty acids which are the biochemical hallmark, the offending metabolite, of ALD, and, stunningly, by eliminating these substances from the bodies of boys who have inherited the ALD gene, but who are simply not old enough for its symptoms to have appeared, Lorenzo's Oil keeps these children symptom-free; that is to say, well, which is to say thank you, God, for using us to help these children, to keep them safe until genetic therapy is ready to delete their effect forever.

In the meantime, what we know Lorenzo's Oil doesn't do is to stop the progression of symptoms in most boys who were already quite symptomatic when they began to take the oil, and we think we understand why this happens. Indeed, not content to be a simple metabolic disorder, ALD is a veritable two-headed monster with

a second auto-immune head known to be analogous to that of multiple sclerosis.

In both of these disorders, inflammation is present in the victims' central nervous systems and is caused by a process involving two main factors—tumor necrosis factor and gamma interferon. Beta interferon recombinant has been shown safely and effectively to reduce the body's manufacture of these substances in multiple sclerosis. It stands to reason that it would be beneficial in ALD as well.

Lorenzo's Oil, although it eliminates the toxic fatty acids from the blood immediately, takes 2 years to remove them from the brain. By dampening the inflammatory process quickly, beta interferon would give Lorenzo's Oil time to reach the brain. It would give the children the time they need. It could quite plausibly—I hate to say "could" because that might be construed as "will"—cut off both heads of the ALD monster.

In other countries, plans are underway for immediate open trials of beta interferon in symptomatic ALD children. The children will be given beta interferon in tandem with Lorenzo's Oil to maximize their chances, to give them hope. The application of open-trial protocols is in harmony with the Declaration of Helsinki, which simply says that the interests of the subjects must always take priority over those of science and society.

In this country, once again lamentably lagging behind in helping the current crop of ALD children, a plan is underway to administer beta interferon in the context of a controlled study with placebo in 1994. In reading the beta interferon protocols of foreign doctors who plan to treat ALD children, it is interesting to note that they had early on considering up a control group with placebo, but that they had quickly discarded this option.

The curve of ALD progression without treatment is very well documented—all of those eloquent small white grave stones, called historical control. Statistics on the naturally history of the disease demonstrate glaringly that the odds for ALD boys still being ambulatory within 18 months of symptom onset are less than even and, within 2 years, highly improbable.

Under the circumstances, opting for a placebo-controlled trial would appear to be as gratuitous as it would be unethical. Children, and frankly American children, are not to be wasted. Their parents are to be educated in the light of and by the light emanating from this bill that they need not offer them up as disposable subjects. I hope you will include this, I beg you to include it, Lorenzo and his buddies implore you to include it in the notion of this bill.

Thank you.

Senator HARKIN. Well, thank you very much, Ms. Odone. We will be back to you with questions as soon as we get through the entire panel.

[The prepared statement of Ms. Odone may be found in the appendix.]

Senator HARKIN. Mr. Vernon Morin, again, welcome, and please proceed with your testimony.

Mr. MORIN. Thank you for this opportunity. I would like to say I am also here on behalf of my daughter, Isabella—we call her

Issy—who is at present 5 years old. She was diagnosed with a deadly cancer, neuroblastoma, at age 3.

Being that we didn't know anything about this cancer, we are learning at as fast a pace as we can. This cancer also is considered an incurable disease. At present, they use chemotherapy, radiation, bone marrow transplants as sole treatments in our conventional medical centers, and even with these treatments, 98 percent of the neuroblastoma cases live only 1 year.

My daughter went through chemotherapy and radiation and was not a candidate for bone marrow transplant. After the therapy, we were told that we should take Issy home and give her pain medication to keep her comfortable, and that she would die within 3 to 4 weeks a painful death. We instead took her home and decided to look into alternative therapies, which we had mentioned to the doctors, who told us that these therapies were ineffective and they would not support them. We also found at that point that our insurance companies would not support them.

We began to use some of these therapies after I researched them myself and made as intelligent a decision as I could make about them, and we began to get instant results with Issy. She was out of pain within 3 days of using Emmanual Revici's, a doctor's, treatment, who uses what he calls nontoxic chemotherapy. This man told us he wasn't sure he could cure our daughter, but he was almost certain he could get her out of pain. Dr. Revici is a 98-year-old man who has been researching cancer and pain for a long time. This treatment, in particular, he has been using since 1960 and it worked well for us.

We combined that with a few other therapies, mainly nutritional therapy, changing Issy's diet, and some vitamins—beta carotene, Vitamin E, and Vitamin C—for particular reasons which I will not go into because it is too lengthy, but basically anti-oxidants, nutritional therapy, and this nontoxic chemotherapy were the reasons, we believe, for Issy's improvement.

Her tumor began to shrink. Issy's pain was gone. She began to act like a normal child, where she was bedridden before and just crying in pain while we gave her pain medication to get her out of pain. Issy became alert. She went back to day care part-time, played with her friends, participated in ballet classes, and until about 4 weeks ago she did beautifully like this. About 4 weeks ago, unfortunately, Issy did start to go have some pain, and we found that the cancer had come back. For what reason—those reasons, of course, we will never know exactly.

However, this treatment has given her quality of life for the last year and we continue to try other therapies at present and we are still very hopeful, even though the doctors from conventional medical centers have continued to put our therapies down and give us negative comments on the therapies, telling us, I told you they wouldn't work, anything you try from here is not going to work, you need to learn to accept the death of your daughter, which we won't. God gave us her life and if he chooses to take it away, then he is the only one that has that right.

We will continue to fight for her life by using other therapies which we believe continue to help her. Even at this moment, they are continuing to help her and she is at this moment battling this

cancer, and she is a very strong little girl. The therapies that we use are researched, and after hearing the statements from the FDA I would just like to say I wouldn't want to have them make the decision of researching the therapies that we go through because it may take 100 years for them to research the therapies that this bill would cover.

Our insurance companies continue to not cover us for these things. It has driven us into somewhat financial devastation, but I might add that God continues to take care of us and Issy, and she continues to fight this, like I said.

The FDA and the NIH have had the opportunity to look at Emmanual Revici's treatment for several years and have denied even looking at it. I was personally given a phone call by the NIH after we were on "Current Affair" last December when Dr. Revici had his license removed and I was told by them, like I said on television this morning, that they wanted me to have people stop calling them. They told me that the FDA knew who we were and that they would make sure that we could not continue to get our medicine.

I told them, all I am doing is trying to save my daughter's life; I don't understand why you won't look at it. The man from the NIH told me they had been trying to look at this medicine for 2 years, but his bosses would not let him. When I asked him who that was, he denied an answer.

All I can say is that if we depend on the NIH Division of Alternative Medicine and the FDA to look at these treatments, my daughter does not have 16 years, like acupuncture has been looked at, and still we have not been given an answer. We don't have 16 years. As a matter of fact, every second is a valuable moment for us in my daughter's fight for life.

I would just like to make an appeal to you that you would include in this bill our opportunity to use some of these well-researched, I might add, therapies and have our insurance cover it so we might find something to help this terrible disease that is taking so many children's lives every year.

When we start to label things as alternative medicine and conventional medicine and traditional medicine and nontraditional medicine, we get away from the learning aspect. We should all be pulling from the same pool of knowledge so we can come up with answers, instead of labeling things with names and fighting over what is traditional and nontraditional. We should all be working together for a cure for some of these terrible diseases that are taking our children's lives.

I might add that Ms. Odone's story, Lorenzo's story, which I had seen, I guess, about halfway through our battle last year, had given my wife and I tremendous strength, seeing what they have done, and allowed us to go on. It does take tremendous strength to fight for your child's life in this kind of a situation because it seems as though there are people around every corner with a baseball bat trying to hit you over the head while you are trying to save your child's life.

I would just like to finish by saying that I would like some help from our Government to try and pull all this information together and make it available to all of us so we can continue to learn and

fight these diseases instead of getting caught in all this sticky red tape because, to tell you the truth, I am getting pretty tangled up and I would like to find a little light here. Help would bring us light, and that is about all I have to say.

Senator HARKIN. Mr. Morin, thank you very much. I have some questions I would like to follow up with you on. Thank you for your testimony and being here.

[The prepared statement of Mr. Morin was not received at the time of printing.]

Senator HARKIN. I want to go next to Congressman Berkley Bedell. I am trying to take you as you are on the list, not as we have you here at the table. The next one is indeed Congressman Bedell, then Mr. Cox, then Mr. Carolla, then Mr. Schauss, and then Dr. Priestley.

Congressman Bedell? Thank you again for being here, Berkley.

Mr. BEDELL. Thank you, Mr. Chairman, for this opportunity to testify on this important legislation. As you know, I have been involved in its formulation and the efforts to perfect it, and it has been a great joy to work with you and with Senator Daschle and with your staffs. I want to especially acknowledge the great work and cooperation of Patty Mitchell on Senator Daschle's staff. Patty has worked long hours in formulating this bill and making corrections when suggestions have come forward for improvement.

As you know, and it has been reported, I left Congress because I came down with lyme disease, which I believe was cured by a special whey product from milk at a cost of about $500, after pharmaceutical treatments that it is estimated had cost $26,000 had not been successful in curing my ailment. I also came down with prostate cancer, as you know, and again it appeared that a $600 alternative treatment was successful after it appeared that my surgeon and radiation, at a cost of $10,000, had not cured my cancer.

It breaks my heart, Mr. Chairman, to have to tell the lyme disease patients that contact me, because their pharmaceutical treatments have not cured them, that the cow's milk type of treatment that I believe cured me is not available because of my understanding and everybody else's understanding of current rules and Government regulations.

Mr. Chairman, we have a serious health problem here in our country. In the United States, it is illegal for anyone, as I understand it, to sell a medicine without spending millions and millions of dollars to get the FDA approval and permission to do so. This causes two problems. First of all, it guarantees that we will not get low-cost medicine in the system. No one is going to spend millions and millions of dollars for permission to sell something unless they can get it patented and a high enough price to get their money back.

Second, it gives a monopoly to the giant pharmaceutical drug firms. Most alternative treatments are nontoxic, nonpatentable, low-cost treatments, and medicines developed by firms and individuals of limited means. They do not have the money to go through the expensive FDA approval process.

The purpose of this legislation is to make it possible for people to try these treatments, while prohibiting sellers from promoting them by making claims of their effectiveness. S. 2140 for the first

time allows the Government to set up a regulated process for individuals and licensed health care practitioners to access the treatment of their choice. Americans who seek more options for their health will no longer have to look to medical bootleggers to provide them with alternative treatment options in the underground or abroad. Practitioners will know that they can be innovative and still be protected, provided they follow the rigorous requirements of this legislation.

Be warned, Mr. Chairman and members of this committee, there are some powerful forces that are doing very well financially under the present system. Pharmaceutical firms and some sectors of organized medicine are seriously threatened by alternative treatments. If lyme disease patients were to be cured by the $500 treatment I received, or if the $600 I spent to overcome cancer were to be common, it would be great for the people, but there are powerful interests that would lose a lot of income.

To defeat this legislation, these special interests can be expected to spend whatever is necessary, using their supporters and the press, some of whom they have convinced that all alternative treatments are quackery. Mr. Chairman, I am living proof that all alternative treatments are not quackery.

It is pretty hard to sell a worthless product without making false claims about its merits. This legislation not only prohibits sellers of alternative medicine from making false claims of effectiveness, it prevents them from making any claims, period. The legislation is tightly drawn. It will not change the FDA approval process. Because of peer pressure, pharmaceutical advertising, malpractice insurance problems, and insurance policies, the vast majority of doctors will not change the way they practice medicine, but it will break the current monopoly and make it possible for people to try some of the alternative treatments, such as the one I used.

Mr. Chairman, our Government was established to serve the people, to protect them from powerful special interests. We have antitrust laws to prevent monopolistic practices. I do not think the Government intended it, but unless laws are changed the Government is a partner in maintaining a monopoly in medicine.

We let people smoke, we let them drink alcohol, we let them gamble, but we will not let someone who is incapacitated with lyme disease be treated with a milk product. What a disaster. I challenge this great Congress, in which I was privileged to serve, to give the people back the freedom of choice they enjoy in almost every other area of our society, a freedom they would enjoy if they lived in some of the other countries of the world, the freedom to choose for themselves the type of medical treatment they desire. I urge every Member of Congress to support this legislation.

Mr. Chairman, I can't tell you how proud it has made me to sit here this morning and hear my colleagues in the Senate as they have expressed themselves on this legislation. I have to tell you it almost brought tears to my eyes from some of the things that I have heard from the members of the Congress.

I agree we ought to do everything we can to make this legislation as good as possible, and we should look at corrections and I think some good ones have been offered. I think, for example, when the

FDA says this should be in writing, I think they are right and we should listen to that.

But I hope that we won't lose sight of the forest for the trees. It is easy to criticize and say this is bad and this is bad and this is bad, and that sort of thing. But we have got a problem and we need to address that problem, and in addressing it the only thing I would say is the thing we cannot do is continue the system which limits the availability of alternative medicines to people by making everyone go through a terribly expensive Government approval process to satisfy a Government agency that nothing can be tried unless they decide that it is sufficiently safe and effective.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much, Berkley, for all of your help in this area for many, many years. I would just say again here for the record that you are living proof that alternative methods work. I was telling some people one time, I said I remember going home and seeing my wife, Ruth, and saying that I had just seen Berkley Bedell, and I said I don't think he is going to be with us much longer. That must have been about, what, 1986, 1987, somewhere in there?

Mr. BEDELL. Yes.

Senator HARKIN. I just thought that you just weren't going to make it and, my gosh, look at you today; you are a specimen of health. I wish you were back here. So you are living proof, and you have done a lot of good for a lot of people in bringing this to the forefront and moving this agenda forward. We are not going to give up on it either; I can assure you of that.

[The prepared statement of Mr. Bedell may be found in the appendix.]

Senator HARKIN. Let's move ahead now to Spencer Cox.

Mr. COX. My name is Spencer Cox and I work as the public affairs associate at the Community Research Initiative on AIDS in New York City. I am also a member of the Treatment Action Group, TAG, and person living with HIV disease.

I would like to start by thanking you for the opportunity to address this committee, and also just very quickly, as long as we are pursuing the idea of freedom of choice, to urge all the members of this committee to support the freedom of all Americans to choose to access basic primary health care by supporting health reform legislation that would include a basic package of health benefits to all Americans.

CRIA is a nonprofit community-based AIDS treatment research program that grew out of the People With AIDS empowerment movement. We believe that until people with AIDS are integrated into every decisionmaking process that affects our lives and our health that those decisionmaking processes are fundamentally unethical.

CRIA is predicated on the notion that real empowerment for people with AIDS and HIV is only meaningful if there is reliable information about the safety and utility of AIDS treatments. Therefore, we are concerned about several aspects of this bill that would offer manufacturers alternatives to the development of the information data bases currently required before treatments are approved for sale.

Programs to ensure that people have access to potentially life-saving experimental treatments have always been and continue to be central to the AIDS activist agenda. We have worked with the FDA and with the pharmaceutical industry to develop regulatory initiatives, such as the treatment IND, the parallel track, the individual use allowance, and the accelerated approval regulations to speed drugs to people.

While we continue to work to build the broadest and most responsive patient access programs possible, these programs have already made substantial progress in ensuring that experimental treatments are made available rapidly to those who urgently need them. Expanded access programs have accompanied development of all of the key treatments for primary HIV disease, including AZT, ddI, ddC, and d4T. More than 20,000 individuals received ddI before approval through a treatment IND protocol. About 10,000 people received ddC, and 16,000 were treated with d4T.

Consequently, for people with serious or life-threatening illnesses, the kind of radical change that is envisioned by this bill is probably unnecessary. That is not to say that all treatments are available, but that we have mechanisms to make them available.

However, these programs are expensive and risky. If a company were to invest in manufacturing for a large-scale pre-approval distribution program and then discover that their therapy was ineffective, they would suffer a significant loss. This committee might usefully explore mechanisms for rewarding companies that invest in these kinds of distribution programs, such as tax breaks on pre-approval manufacturing costs.

It is important to ensure also that we protect the safety of all people with life-threatening illnesses, including people with HIV/AIDS, and that we collect reliable information on the efficacy of medical treatments. We are very concerned about the safety provisions of this bill mainly because of two alterations in the way that we regulate safety.

First, this bill seems to assume that drugs and medical devices are safe until they are proven otherwise. This assumption is sadly unjustified by our experience with drug development.

Second, it shifts the burden for proving that a drug or medical device is safe or unsafe from the manufacturer to the FDA. There seems to be an unspoken idea that providers would be able to tell if a treatment was harming rather than helping patients. This would be true if the therapy were causing gross harm, such as the recent experimental hepatitis B treatment, FIAU, which caused liver failure in most of the patients who were treated with the drug.

However, it is not necessarily true of treatments that cause more infrequent, less drastic, or longer-term toxicities, as I think FDA pointed out. Particularly in chronic, degenerative diseases, side effects are very difficult to distinguish from disease processes and their detection usually requires randomized controlled clinical trials.

I am also concerned that the informed consent provisions of the bill allow the sponsor too much latitude in determining what baseline information must be developed on new treatments to inform the practice of health care providers. Although the bill requires

that patients be informed of any reasonably foreseeable side effects, it contains no mechanism for ensuring that common and/or serious side effects could reasonably be foreseen.

Simply telling patients that a drug is available and that no one knows whether it is safe and effective could actually reduce the quality of AIDS care by persuading people with AIDS to forgo truly effective AIDS treatments. Furthermore, such warnings provide little that is useful in making treatment decisions.

After recent data raised questions about early studies showing benefit to treatment with AZT early in the course of HIV disease, the Public Health Service produced a set of recommendations that patients and their physicians, quote, unquote, "consider treatment" before the onset of full-blown AIDS.

I see two physicians, each of whom has a different pattern of prescribing AZT, and each of whom acknowledges that he is uncertain about his own method. The drugs that are available to treat HIV are not benign. Their use is often accompanied by debilitating and even fatal side effects. A recommendation to consider treatment has not been terribly helpful in determining whether or not to risk early treatment.

I have yet to find a mechanism that is as effective as regulation of drug sales to ensure that manufacturers develop the information that will inform both provider's practice and patient's choice. In AIDS, it has been more productive to allow patients with few therapeutic options to access experimental treatments while continuing to regulate the safety and efficacy data that are required to market the treatment.

Consequently, I am concerned that the Access to Medical Treatment Act would have the unintentional effect of presenting practical disincentives for sponsors to evaluate the safety and efficacy of new treatments. Large companies with a name and reputation and stock prices to look after would probably continue to study drug safety much as they do now. However, large-scale efficacy studies which are required in order to determine whether or not a treatment really works are expensive, time-consuming, and laborious, as has been testified to over and over again today.

By divorcing marketing rights from the conduct of these studies, this bill could cause pharmaceutical companies to view efficacy testing as a fiscal luxury. Small companies doing clinical research would certainly be at a financial disadvantage in comparison to other small companies that just skip the testing phase altogether. As one executive from a large multinational pharmaceutical company recently told me, pharmaceutical companies have an obligation to their stockholders not to conduct expensive studies that exceed the regulatory requirements.

Finally, I would like to say that although I am troubled by some of the specific mechanisms by which this bill would achieve its goal, I remain strongly committed to the overall effort to provide patient access to experimental therapies, and I am grateful that this committee has taken the time to consider the proposal. I would hope that my comments would not discourage the committee from continuing to work on these issues, but would instead offer direction for future initiatives.

Just very quickly, what I would think about in terms of any future initiatives, first, is that proving that a drug is both safe and effective is the best mechanism for ensuring widespread access to new therapies, including getting insurance companies to pay for them. Consequently, efforts to expand access should include incentives for controlled research, possibly including funding for study of, quote, unquote, "unorthodox treatment modalities," such as acupuncture, and for unpatented treatments that may lack corporate sponsorship for research.

At CRIA where I work, one of our board members, Dr. Donald Cotler from St. Luke's Roosevelt in New York, produced some very interesting test tube data suggesting that aspirin may be useful in the treatment of HIV disease. Obviously, that is not a patentable therapy and so we set out to raise the money to begin doing clinical trials. In fact, those studies are ongoing right now.

I would add that efforts to expand access to experimental therapies should retain strict regulatory control over the safety of new therapies, and companies should be offered incentives such as tax deductions to make therapies widely available before approval through expanded access programs, such as parallel track.

Thank you.

Senator HARKIN. Thank you very much, Mr. Cox, for your testimony.

[The prepared statement of Mr. Cox may be found in the appendix.]

Senator HARKIN. Next, Mr. Carolla. Welcome.

Mr. CAROLLA. Thank you, Mr. Chairman. My name is Bob Carolla. I am legislative counsel for Consumers Union, a nonprofit membership organization that publishes Consumer Reports and other consumer publications.

Consumers Union recognizes that conventional medicine doesn't have all the answers and alternative treatments can offer benefits to consumers. Earlier this year, Consumers Union published a three-part series on alternative medicine in Consumer Reports focusing on acupuncture, homeopathy, and chiropractic. We found that studies of alternative treatments are few and that most are poorly designed.

In preparing the series, we had to sort through too little science and too many conflicting claims, shibboleths, and hopeful hypotheses in order to provide guidance for consumer choice. We expressed strong concern over practitioners of alternative remedies who rely on anecdotal evidence or theories that aren't supported by competent research.

Mr. Chairman, for the hearing record I would like to offer as an appendix to the record copies of that series that appeared earlier this year.

Senator HARKIN. Without objection, I will include that.

[The information referred to is retained in the files of the committee.]

Mr. CAROLLA. Consumers need to be informed, knowledgeable and involved in their treatment choices, and they have to exercise informed consent. In introducing S. 2140, Senator Daschle indicated that the bill represents a best first attempt to reconcile what may seem like two irreconcilable interests; namely, consumer pro-

tection from unscrupulous charlatans, and the consumer freedom to choose. We commend Senator Daschle for that effort and his intentions in the overall bill.

Consumers need protection, however, not just from charlatans, but also from undue or unknown risks. Freedom of choice becomes an empty concern in the absence of an adequate base of knowledge on which to exercise informed consent. For this reason, Consumers Union opposes S. 2140. It neither enhances consumer safety, nor provides for greater consumer information.

As reflected in the discussion with FDA earlier this morning, there may be some question as to whether the bill is even necessary for the purposes that it seeks to serve, and a preferable alternative might be to work to build on existing law and to improve and clarify existing FDA review and approval processes.

As it is presently drafted, we believe S. 2140 is not only a bypass of FDA, but also a step in the wrong direction in the development of the law. In the March 1994 issue of Consumer Reports, for example, we called on Congress to repeal the existing exemption for homeopathic remedies under the Food, Drug, and Cosmetic Act's testing requirements for safety and efficacy.

S. 2140 shifts the fundamental presumption under the Food, Drug, and Cosmetic Act and stands the FDA regulatory process on its head. Ordinarily, a treatment must first be proven safe before it is no longer considered to be dangerous. This burden of proof provides the highest degree of consumer protection. In contract, the bill shifts the presumption so that a treatment only must show no evidence of being dangerous.

This "no evidence" standard is doubly troublesome because there are no testing requirements in the legislation. The risks of a treatment therefore might only be found on a trial-and-error basis. The bill's definition of "danger" also allows for negative reactions that are no more serious than those experienced with routinely used treatments for the same health problems. It, furthermore, allows for treatment if there is informed consent of reasonably foreseeable side effects. In both instances, the bill seems to assume some level of prior knowledge about a particular treatment. However, there is nothing in the bill that would require the kind of testing and evaluation upon which to base such knowledge, let alone informed consent.

Regrettably, the bill is an open invitation to practitioners to use human patients as laboratory mice in unorthodox, eccentric, or even reckless experimentation. It provides no advance assurances of consumer safety. It does not provide for any careful, systematic assessment of proposed treatments.

The bill does intend that knowledge of dangers gained by experience through actual treatments be shared and relied upon. However, here, too, we consider the bill to be flawed. Under Section 4, a reporting requirement exists if a treatment is discovered to pose a danger. However, no explicit civil or criminal penalties exist for any failure to report any such discovery. Enforcement of this requirement is essential, especially if one is to build a record of information about a particular treatment. But as a practical matter, we fear that enforcement will be difficult.

Under Section 2's definition of "danger," furthermore, negative reactions are tolerated if they are no more serious than those for conventional treatments. An entire category of potential side effects which are relevant for consumers giving informed consent therefore is left uncovered by Section 4.

The bill also seeks to promote consumer protection through its provision in Section 3(b)(4) that no claims can be made, including through advertising or labeling, with respect to the efficacy of a treatment. However, there are exceptions to this provision. Consumers Union supports the principle of open communication between practitioners and patients which are reflected in two of the exceptions. Concern exists, however, for instances in which there may be an excess of enthusiasm on the part of a practitioner, particularly where the practitioner is an apostle of a particular alternative school of treatment.

Informed consent requires full communication and understanding of treatment alternatives, which is not necessarily promoted by the legislation. A New England Journal of Medicine study published in 1993 has indicated that 72 percent of people who use alternative treatments don't tell their regular doctors what they are doing.

If alternative treatments lead a patient to forgo conventional treatment by a regular physician, the result in some cases can be fatal. S. 2140 fails to protect consumer interests through any specification that an alternative treatment should be used either only as an adjunct to regular medical treatment or only after conventional remedies have been exhausted.

In conclusion, Consumers Union opposes S. 2140 because we see it as fundamentally flawed. It shifts the presumption that underlies existing standards of consumer protection. It permits treatments without any prior testing and evaluation. It does not provide for the systematic collection of information on which to base informed consent, and it does not adequately protect consumers against unknown risks.

We are sympathetic to patients who seek alternative treatments when conventional medicine lacks comforting or immediate answers. However, even with the best of intentions, the bill leaves consumers vulnerable to false hopes and undue harm. We urge you to consider other alternative approaches in seeking to support the laudable goal of promoting sound alternative treatments.

Senator HARKIN. Thank you, Mr. Carolla.

[The prepared statement of Mr. Carolla may be found in the appendix.]

Senator HARKIN. Now, we will turn to Mr. Alexander Schauss.

Mr. SCHAUSS. Thank you, Mr. Chairman, for the opportunity to testify at this hearing today. My name is Alexander Schauss, Ph.D., executive director of Citizens for Health, a national nonprofit consumer health advocacy organization with members in 11 countries and over 150 chapters in all 50 States.

In 1985, I was appointed a member of the World Health Organization Study Group on Health Promotion that met in Copenhagen, and have maintained numerous professional and scientific memberships and affiliations in public health organizations.

However, besides being an association executive, I also am a research psychologist, a certified eating disorders therapist, a board-certified counselor, and certified mental health counselor who has held various administrative positions for social service agencies in New Mexico, South Dakota, and Washington State.

Imagine two fully loaded passenger jet liners colliding in mid-air with all passengers on both planes killed, with such collisions occurring every day of every week, 365 days a year. Now, you have a sense of the number of deaths reported each year due to adverse reactions to drugs approved by the FDA, and that doesn't even take into account all of the tens of millions of hospital days caused by these FDA-approved products. Conventional medicine is not as safe or effective as we have been led to believe.

By comparison, I reviewed the data for every year since 1982 compiled by the American Association of Poison Control Centers and published in the Journal of Emergency Medicine. I could not find one case of a death due to a commercial herbal product or an uncontaminated nutrient, and only a small number of cases associated with iron poisoning by young children or infants. These unpatentable herbal and nutritional products could save this country hundreds of millions of dollars in reduced health care costs, but these natural remedies will never get by the FDA's drug review process, which some estimate costs in excess of $200 million to complete.

It was the great American inventor and scientist Thomas Edison who said over 100 years ago, quote, "The doctor of the future will have no medicine, but will interest his patients in the care of the human frame in diet and in the cause and prevention of disease," unquote. I am sorry to say that in 1994 we are still a long way from that kind of health care system.

Medical students still receive virtually no training in nutrition or nondrug therapies, such as homeopathy, chiropractic, naturopathy, or acupuncture. What medical students do receive is an average of 1,887 hours of training in the use of drugs. So is it any wonder that we have in this country a conflict between chemical doctors and natural doctors?

However, this conflict is detrimental to health care consumers. Patients must have access to those licensed providers who are trained in the use of safe, effective, and cost-effective natural treatments. Just take my own mother's experience several years ago. After 5 years of significant side effects from taking various ineffective medications for her ulcers, at the insistence of her doctors she agreed to surgery, at a cost of $10,000. But she also visited a naturopathic physician for a second opinion. The naturopathic physician promptly took her off the $190 a month of drugs she was taking and placed her on a herbal licorice root product which she bought from a local health food store for approximately $15 per month.

Her ulcers literally disappeared within 4 months, much to the amazement of her internist and gastroenterologist, who had never heard of this safe and effective therapy. When she asked them why, they responded that they had never been educated about treatments other than drug therapy for this condition in medical school training.

I found that this therapy is fairly routine for ulcers in many other countries. Then why shouldn't all Americans be assured that they can have access to such alternative therapies if they are fully informed of any risks associated with choosing such treatment, as is proposed in this bill?

Critics would claim that this legislation would open the door to quackery because it would allow doctors to give their patients remedies that are not FDA approved. But isn't it quackery to have my mother suffer needlessly for 5 years and $16,000 of worthless drugs, tests, and treatments that failed to improve her condition? The definition of quackery as used by these critics is a mindless definition—quote, "If it isn't a drug or conventional therapy, it is automatically quackery," unquote.

Germany had the same kind of critics in the 1970's that I expect will be here criticizing this bill. But in 1976, it had the wisdom to pass a law that opened up access to all kinds of medical treatments administered by licensed practitioners.

I think this bill is right on target. Thousands of nonFDA-approved alternative treatments that are gathering dust could be used to treat conditions and save money when other prevailing conventional treatments have failed. For example, conventional treatments for chronic back problems can cost $40,000 if the patient has surgery. However, if the patient has 1 month of chiropractic care, combined with acupuncture, it could cost less than $500, a substantial savings. In my mother's case, the savings was close to 10,000 percent.

Since there is no rational regulatory mechanism for herbs, herbal products, or nutrients to determine their safety and efficacy, there cannot be reasonable warnings and/or contraindications to guide the consumer or health practitioner on its use. The current system puts the burden of appropriate use recommendations and/or safety considerations squarely on the shoulders of the health professional, without any authoritative guidance. In other industrialized nations, such as Germany, France, and Canada, rational regulatory systems for approved drug claims, for example, give professionals and consumers this needed guidance.

The committee will be pleased to hear from our esteemed visitor from Germany that quackery has not been rampant in his country, but quite the opposite has occurred. In 1993, the German medical system had been convinced of the importance of many of these alternatives. Now, all German medical students are required to pass a section on their final exams on the use of herbs in the prevention and treatment of disease. Soon, dietary supplements will follow.

This bill expands the selection of medical treatments available for illness so that patients have other options when conventional methods fail. This legislation will not undermine the FDA's authority or detract from the conventional medical community or pharmaceutical industry. Rather, it will open up the consumer market to low-cost, safe, and effective alternative therapies.

Consumers also benefit from the bill's requirement of full disclosure of the contents and possible side effects of treatments, as well as mandates that patients are notified that the remedy has not been proven safe or efficacious according to FDA standards.

Let me end my testimony by reading three sentences written over 200 years ago by Benjamin Rush, M.D., one of the signers of the Declaration of Independence. Quote, "The Constitution of this republic should make special provisions for medical freedom, as well as religious freedom. To restrict the art of healing to one class of man and deny equal privileges to others will constitute the bastille of medical sciences. All such laws are un-American and despotic," unquote. The freedom to choose one's own form of health care should be a fundamental right of Americans. This reason alone explains why Congress should support this important legislation.

I wish to thank the committee for inviting me to testify before this historic hearing today. Thank you.

Senator HARKIN. Thank you very much, Mr. Schauss.

[The prepared statement of Mr. Schauss may be found in the appendix.]

Senator HARKIN. Next, we have Dr. Joan Priestley. Now, you were added later on. I do not have a copy of any written testimony. Do you have such?

Dr. PRIESTLEY. Yes, I have one for you. Thank you very much for asking me to comment on some of the things——

Senator HARKIN. Excuse me just a moment. I do not have a copy of your testimony. Did you have any copies made?

Dr. PRIESTLEY. Yes. I have numerous copies which I can give you.

Senator HARKIN. Again, Joan Priestley, M.D., executive vice president for government affairs for Citizens for Health. That is the same organization of which you, Mr. Schauss, are the executive director, is it not?

Mr. SCHAUSS. Right, correct.

Senator HARKIN. All right. I have a copy of your testimony, Dr. Priestley. You are an M.D. and you are from where, California?

Dr. PRIESTLEY. Yes, sir.

Senator HARKIN. Please proceed.

Dr. PRIESTLEY. Thank you for asking me to comment on some of the things that have been discussed here. I would like to refer to a couple of parts of my testimony and then I would like to comment on some of the inaccuracies and selective omissions which have been discussed by the FDA because the picture they present to you is not the picture that has been presented to health practitioners and the public.

First of all, I applaud your interest in holding this historic hearing and in promoting this extraordinary legislation. Sovereignty begins with our own bodies. We absolutely have the right as free citizens and sovereigns to determine what we are going to put in our bodies, what we are going to keep in our bodies, and what kinds of choices we are going to make for health care in America. However, we have a lot of trouble with certain Government agencies implementing those choices.

The claim has always been raised that alternative therapies will lure unsuspecting, vulnerable people away from conventional therapies which are safe and effective. I would just like to refer you to page 2 of my testimony because people who make those claims seem to have forgotten the 1990 GAO report from the General Ac-

counting Office that concluded that over half of the drugs approved as safe by the FDA between 1976 and 1985 caused such serious side effects that they required relabeling of the drug or its outright withdrawal from the market—over half.

These side effects were described in the report as being common, and resulted in hospitalization, permanent disability, and even death. Another member of the House of Representatives commented at that time that this report was an important reminder that FDA approval does not guarantee that approved drugs are safe.

As for effectiveness, I as a physician have been using holistic therapies from around the world since 1982. I wouldn't do this kind of medicine if it didn't work better, with less toxicity, less worry to me and my patients, than conventional therapies that I was trained to use as a medical doctor at the University of Michigan.

I would like to briefly review several points that were inaccurately conveyed to you by the members of the FDA because I think they are very important. No. 1, Ms. Pendergast neglected to include the intended use doctrine which they have published in their final rules on January 4 of this year. According to the intended use doctrine, it doesn't matter if a company has omitted all claims from its label and refuses to make any other information available. If the FDA can show that in the minds of consumers, or the manufacturer or vendor, the product is intended to be used medicinally, that alone is sufficient to confiscate the product and keep it from people's hands. So the intended use doctrine is new and it is very important, and we will see it used.

Senator HARKIN. When was that promulgated?

Dr. PRIESTLEY. It was published in the final rules which they published on January 4 of this year relating to dietary supplements.

It is not just a matter of a company making claims on their label or in labeling, which brings me to my second point. Labeling encompasses many things. It encompasses what is on the bottle. In a label "sleepy time tea," for instance, that is a medical claim, according to the FDA, on the label of the tea. However, if the company makes available any information, literature, reprints of medical journal articles on independent research about that ingredient, not even that brand, but just that ingredient—if the company makes that literature available to anyone, that is considered labeling the product, and that literature will be pointed to as sufficient reason to confiscate the product and the FDA has done this many times.

I am a licensed medical doctor. I have been through medical school. I have called up companies when I have heard about a new product or seen something new that is theirs on the shelf, and I have said, can you just give me your research so I know what the side effects are, what the dosage is; what should I tell my patients, how should I use it? They have said to me, I am sorry, Dr. Priestley, we can't make any information available to you because the FDA would consider that labeling the product. So I as a medical doctor am deprived of information I need and desire to be able to evaluate products effectively.

One company which has had severe problems with the FDA was still willing to make information available to me. They sent it to an employee of their own who works in Canada. The employee used a mail drop from Canada under a different name and sent me their monographs, which come from Germany, I should add, because they are importing German products. That is what it has come to for me as a doctor to get information about alternative therapies from the companies.

They also said, and I should quote—Ms. Pendergast said they go after companies when companies make claims they can't support by scientific evidence. I think you understand that it is not about companies making claims that are not supported by scientific evidence. It is about companies making claims that are not approved by the FDA. The FDA has, I feel, deliberately confused the issue of unsubstantiated claims, unproven claims, with unapproved claims. There is a vast difference. It is not that companies make unsubstantiated claims. If they make any information available whatsoever without prior FDA approval, that is grounds to confiscate their products at gunpoint.

I would like to explain my personal fears about my practice. The FDA has engaged in armed raids of medical practitioners with marshals and sheriffs and police departments. They have gone in with guns drawn to doctors' offices. So when Ms. Pendergast says that practitioners are outside their jurisdiction, that is not correct. They have raided doctors' offices for using unapproved medical devices, such as ozone equipment, and for using unapproved new drugs, such as vitamins, without getting prior FDA approval. I am afraid every day that that will happen to me.

I have evaluated ozone extensively. I decided not to use it in my practice, not because it didn't work medically. It has tremendous benefit medically and, as you said, it is used in Germany and other countries, and has been since World War II. I decided not to use ozone because it puts me at too great a risk professionally from raids from the FDA. They are well known to confiscate ozone equipment on sight when they even see it in a doctor's office.

She also neglected to tell you about Dr. Brezinski in Texas, who has been the target of innumerable FDA actions because he has developed a cancer treatment that works, but it hasn't been approved by the FDA; no patient complaints, just that the FDA has moved on its own decisions.

I joined a group called Search Alliance, which is an organization of medical doctors in Los Angeles. We research new therapies and alternative treatments for AIDS. We decided to form this alliance because the first physicians who were on their own researching alternative AIDS treatments almost went to jail at the hands of the FDA, the Attorney General's office, and the medical board. We decided to ban together and do joint projects on the theory that they can't incarcerate us all.

The FDA, I think, has revealed its true colors. When they say that they want to encourage new products to get on the market and alternative therapies to be available to people, the reality of their regulatory history doesn't support that contention. What they have done recently is remove several products from the market within about a month of announcing the approval of a drug that would

treat the same illness, although the herbal products have been shown in trials—when they compare the herbs to the drugs, the herbs work better, and I list three examples in my testimony for you when they have done that.

This is not consumer protection. It seems to me that the health they are most interested in protecting is that of the multinational pharmaceutical companies, and that is why I applaud your willingness to provide legislation that will protect our basic freedom to have a private relationship between a patient and a practitioner, for us to discuss and take and utilize whatever particular therapy those two individuals privately decide will work for the patient.

Thank you very much for this opportunity to comment on the other statements that were made.

[The prepared statement of Dr. Priestley may be found in the appendix.]

Senator HARKIN. Thank you very much, Dr. Priestley. I was reading your testimony. Would you go back to your first page here? There is something you left out there. You said, "Since 1986, I have used an array of natural products to treat over 700 AIDS patients."

Dr. PRIESTLEY. Yes, that is correct.

Senator HARKIN. Tell me about that.

Dr. PRIESTLEY. Well, I have been a specialist in immune system problems. It was very evident from the first patient who walked into my office with HIV infection that the traditional drugs were doing marginal, transient benefit, at best, and therefore this is an area where we need to be more creative and more courageous both as physicians and as patients. I will send to your office a study which I have done on my own patients which I have presented at the last three international AIDS conferences.

Basically, I am bored with my practice. My clients very rarely get sick. It is exceedingly rare that they have to go into the hospital, and it is next to unheard of that they die. Most AIDS doctors don't have this experience whatsoever. I use a program of diet changes, attitude adjustment, and a raft of dietary supplements and products from around the world on my clients.

I should add, also, that we have begged repeatedly, and I mean begged, the FDA to fund trials of these products, including garlic, which is the first choice of product in the Orient for very severe fungal infections. I have personally reversed people who were 36 hours away from death by using intravenous garlic extract. We brought it in from China. However, I could go to jail for doing so.

Senator HARKIN. I was going to say, was that an approved practice by the FDA?

Dr. PRIESTLEY. Hardly. We have begged them to fund trials of the various herbs and things that I have seen work dramatically effectively on my clients, and we might as well talk to a wall; we just get nowhere over there. If it is not a product that has commercial merit, they have said point blank that we can forget it.

But in summary of my AIDS patients, they live quality lives and they live far longer than they are statistically expected to. The vast majority of my patients remain free of symptoms and free of significant side effects. They are working. They jog around Los Angeles. That may cause its own health risk, but many of them are in better shape than I am. They just have no immune system. These

nutrients and products that I give them to a large extent can take over the functions of their own depleted immune system.

Senator HARKIN. Thank you very much, Dr. Priestley, and thank you all for your testimony.

We are joined by our distinguished Senator Pell, who has had a long and intense interest in the area of alternative medicine. In fact, Senator Pell gave me once a book which I have in my office—it is about that thick, a couple of inches thick, for the record—of cases of spontaneous remissions. I have often wondered why we have never had an intensive survey done of spontaneous remissions to categorize, to classify, to find out what are the profiles of these people.

If you had cancer and went into spontaneous remission, well, who are you, what did you eat, how did you live? And then somebody else had a spontaneous remission; how did you eat, what did you do, and sort of get a whole matrix and a profile built of these things. We might be able to find some information. Nothing is done on this, nothing whatsoever.

I appreciated your bringing that to my attention, Senator Pell, and I would yield to you for any opening statement or for any questions you might have for the panel.

OPENING STATEMENT OF SENATOR PELL

Senator PELL. Thank you very much. Actually, there is an index of cases of spontaneous remission that Dr. O'Regan of the Noetics Institute pulled together.

Senator HARKIN. Right; that is what you gave me.

Senator PELL. I think that is what I gave you.

Senator HARKIN. That is what you gave me, right.

Senator PELL. I just believe in the idea that we don't have a monopoly on the ways of doing it; that natural methods and herbs and other devices should be accepted. As of now, the average M.D. doesn't necessarily laugh, but turns a blind eye to these suggestions.

I am just very glad that this hearing is being held. I am very glad that Senator Daschle has introduced this legislation. Congressman Bedell and I are old friends, and I just wish you good luck in what you are doing.

Senator Daschle [presiding]. Thank you, Senator Pell. As Senator Harkin has indicated, prior to the time Senator Harkin and I became interested, Senator Pell was privately and publicly advocating many of the things that this bill has addressed, and we deeply appreciate his involvement over so many of these years.

Let me also add my gratitude to the whole panel. It is a very eclectic panel, needless to say, but it certainly has been an enlightening experience for me to read the testimony and then to hear the final witnesses as you presented your oral testimony this morning.

I prefer in my hearings to try and generate as much exchange and interaction among the witnesses as possible after the prepared testimony because I think there is where some of the truth can be brought out. I would be interested, Mr. Carolla, in your reaction to the comments of the other witnesses on this panel. As a consumer advocate, what do you think?

Mr. CAROLLA. I think at one point the words were used that here was a safe and effective herbal remedy, and I immediately started to think how was it known that it was safe and effective, which mirrors what the standard is under existing law, not even the standard that would be under the bill.

How do you take any substance, any kind of treatment, wherever you find it and make an initial determination, gee, this might be something that works, and at the same time start a process by which you are protecting consumer safety in not simply using something without having done the kind of research that is necessary before you start down the road toward a wider and wider use?

Senator DASCHLE. We need to be careful of how we are describing these things. You say any kind of research. I don't know that anyone has advocated the utilization of a product with absolutely no research. The question is, and it goes back to the original problem that all of us have presented—the question is, are there situations where it is legitimate to allow access before going through the elaborate hoops, the extraordinary cost, the incredible length to get to the point of FDA approval, especially when, as Dr. Schauss has indicated, hundreds of people die having experienced products for which that process was already completed? That process is no assurance of quality or of safety in all cases.

As has been indicated by testimony, it would appear that if one looks at statistics, you are not necessarily guaranteed safety simply for having gone through that process if deaths and illness are any kind of indicator. How would you respond to that?

Mr. CAROLLA. I don't know how you ensure consumer safety, let alone any standard of effectiveness, if you don't do some very basic testing and evaluation. Part of our concern is that there may be an assumption, but there is no requirement under the bill as written of that happening and it is an enormous loophole. That is how we see the bill.

I am not saying that there aren't promising treatments and remedies out there that should be looked at, should be tested, should be funded. The Office of Alternative Medicine at NIH has begun some of that process, I think, with a $2 million appropriation. It is probably not enough.

Senator HARKIN [presiding]. I don't know of anyone who has been a stronger consumer advocate in all his years that I have known him, and it has been a long time, than Berkley Bedell. Berkley, how would you respond? You have been a strong advocate of consumers. There was not a stronger fighter for the little person here in Congress all the years he was here. How do you respond to what Mr. Carolla is saying on consumers and how they are protected?

Mr. BEDELL. Well, that is the whole issue. The whole issue is does the Government know better than anybody else what is best for people. I should tell you I was chairman of the agriculture subcommittee that had to do with chemicals for crab grass, and it took 7 years and $7 million to get FDA approval to be able to sell a chemical to kill crab grass. It took longer and cost more money to satisfy the FDA that it killed crab grass than to prove it was safe.

I always said you ought to prove it is safe, but it is ridiculous to spend all this money for some Government to decide whether

something is effective or not. The market does that very clearly, and especially in this bill when you can't make any claims. I always said I hope to God the Government doesn't ever get to where you can't sell a fishing lure unless some bureaucrat has decided it caught fish. [Laughter.] [Applause.]

That is the whole issue here. The issue is should people have the right to choose when properly informed, and I am telling you the pharmaceutical industry and the people involved with that don't want that to happen. You are a consumer advocate, and Senator Pell is and Senator Daschle is, and we have to have the guts and the courage to stand up to those special interests and say, no matter who all they may convince that we shouldn't give people that trial, we have got to say we have got the courage and we are going to fight to have it done.

I can tell you one thing; it is going to be done. I don't know when, but the people are starting to demand it more and more and more, and the people of America are not going to sit here and continue to give monopoly to the pharmaceutical industry in terms of medicine when other countries are experiencing better results because they have removed that and because the people are recognizing that for many of these treatments pharmaceutical drugs do not have the answer.

I have told you before how proud I am. You weren't here, Senator Daschle. I am so proud of having served with you, and I am so proud of what you have had to say today and I am so proud of your bringing up this legislation. There is going to be criticism of you—you know that—for doing so, and everybody is not going to agree with you, but I am so proud of what all of you have said. And, Senator Pell, you are a leader in this, and I apologize for taking so much time.

We want to be sure that people know, when they couldn't give testimony, that they can enter it for the record. I think you forgot to mention that, but would you be sure?

Senator HARKIN. I didn't mention that, but I would, certainly. I usually do that at the end of the hearing.

Mr. BEDELL. OK, just so we are sure that people know because I know a lot of people wanted to testify that could not testify.

Senator HARKIN. I will mention that at the end, but you brought it up. Certainly, the record will be left open for additional testimony that anyone would like to offer, and I will leave it open for a certain period of time. I will figure out how long.

I am sorry, Senator Daschle. I didn't mean to interrupt.

Senator DASCHLE. Well, Mr. Chairman, thank you. I have to apologize. Secretary Pena has asked for a meeting at 12:00 and I am going to have to excuse myself, but I must say I miss that Bedell passion and truthfulness.

Senator HARKIN. That is true.

Senator DASCHLE. It is just refreshing to be around this place for as long as we have and to be reminded again that public service is a very high calling. We were honored to have Berk Bedell set a standard that not many of us are able to reach with any consistency. He has demonstrated once again how high that standard is this morning, and I applaud him and I thank all of you.

As Congressman Bedell has said, we may not pass this bill this year. We may not pass it in the foreseeable future, but it, or something like it, will pass. I can say for a lot of those who may not be here this morning that this is just the beginning and we are going to hang in there. We are going to do this. Sooner or later, it is going to happen because of the people assembled here and the thousands they represent. It is the right thing to do, and we will do it.

Thank you very much, Mr. Chairman, for giving me the opportunity to be part of this.

Senator HARKIN. Thank you, Senator Daschle. I understand that you have to run.

Senator Pell?

Senator PELL. I too have to go, but I just wanted to maybe submit a question for the record for Mr. Carolla.

Senator HARKIN. Absolutely.

[The question of Senator Pell follows:]

Senator PELL. Mr. Carolla, you testified that "(i)f alternative treatment leads a patient to forgo conventional treatment by a regular physician, the result in some cases can be fatal" and charged that this bill "fails to protect consumer interests through any specification that an alternative treatment should be used only as an adjunct to regular medical treatment or only after conventional remedies have been exhausted."

Suppose this bill were amended to specify that alternative treatments may be used freely when 1) used as an adjunct to regular medical treatment, or 2) after conventional remedies have failed.

Would you and Consumers Union then be able to support this legislation.

Mr. CAROLLA. Such a requirement could be an important improvement to ensure physician-patient communication and to ensure necessary and proper treatment. However, the principal source of Consumers Union's opposition to the bill is creation of a "no evidence of danger" standard without any testing and evaluation requirement. Because of that concern, we see the bill as fundamentally flawed. One alternative might be to build on existing standards under the Food, Drug and Cosmetic Act (FDCA) and to clarify or refine existing review processes by the Food and Drug Administration (FDA). There may be other alternative approaches. Consumers Union is willing to work with the committee to explore all possible alternatives and improvements to the bill. We welcome the opportunity to do so. We are sympathetic to the intentions of the bill's sponsors, but for all the reasons outlined in my testimony, we must oppose the bill in its current form. We will be glad to consider support for the legislation if appropriate changes can be made.

Senator HARKIN. I am really sorry that the time has run at this point because we have Dr. Schurholz from Germany and I really wanted more Senators to hear Dr. Schurholz' testimony. I do not know him. I have not met him. I will meet him shortly, but I have seen his testimony and it really is enlightening what is happening in Germany, which, as I pointed out, is not a neolithic country. What they are doing there is incredible.

Senator PELL. I look forward to at least reading it.

Senator HARKIN. I will make sure you get his testimony.

Senator PELL. Thank you.

Senator DASCHLE. Mr. Chairman, I would also invite Dr. Schurholz to come by my office if he has time today. I would like to personally meet him and talk with him if it were not possible to be here to hear his testimony directly. If we could do that, I would very much like that.

Senator HARKIN. I appreciate that. He knows it now, so we will make sure and see if there is time for that.

Mr. MORIN. Senator Harkin?

Senator HARKIN. Yes?

Mr. MORIN. I have to catch a flight, so I am also going to have to leave. It is the only flight going back to where I am coming from and I need to get there.

Senator HARKIN. Well, you are not going to leave until I ask you one question.

Mr. MORIN. I am going to miss it. It is at 12:30. I have to go back to the hotel and then go to the airport.

Senator HARKIN. Oh, my goodness. Well, listen, you brought up something that I have got to ask you about because you mentioned it this morning. You said that you received a phone call from the NIH?

Mr. MORIN. Correct.

Senator HARKIN. Tell me again what they said to you. They called you?

Mr. MORIN. Correct. This was after I was on "Current Affair," and they had taken Dr. Revici's license away and I had tried to make a public appeal to get back the medicine that we were using. We had not run out of it yet, thank God, but we didn't want to run out. They called me and told me to stop having so many people call them. I never told anyone to call them, but I guess people had seen the show and they had been led to call the NIH, for some reason or another.

I was told that the FDA knew who I was, which really didn't concern me.

Senator HARKIN. You mean this person at the NIH said that?

Mr. MORIN. Correct.

Senator HARKIN. Yes.

Mr. MORIN. And they said that they would make sure that my daughter would not get the medications that she needed unless I told people to stop harassing them, and I told him that I would get off the phone and tell everyone what he had just told me. That just goes to show you that there are people out there threatening us as citizens about using these things that we are just trying to save our children with.

I understand this man down here wants to protect us as citizens. Of course, the State of——

Senator HARKIN. I want to ask you, Mr. Morin, will you State for the record who that individual identified himself as who called you up?

Mr. MORIN. He is the head of the alternative medicine division of the NIH, and I believe, and I may not have the name right—I know the last name is Jacobs, I believe. I think it is——

Senator HARKIN. And he identified himself——

Mr. MORIN. I could identify it if I had in front of me because I have the name written down at home, but I believe it was a Dr. Jacobs.

Senator HARKIN. Yes, of the Office of Alternative Medicine?

Mr. MORIN. Correct.

Senator HARKIN. This individual called you?

Mr. MORIN. Correct.

Senator HARKIN. And at least you inferred from his tone or what he said that he was somehow threatening you?

Mr. MORIN. That is the way that I interpreted his phone call.

Senator HARKIN. In other words, he didn't call you and say, I am from the Office of Alternative Medicine and I want to help you get through this mess?

Mr. MORIN. No, he did not say that to me.

Senator HARKIN. This was Dr. Jacobs?

Mr. MORIN. Correct.

Senator HARKIN. From NIH?

Mr. MORIN. Correct.

Senator HARKIN. He will hear from me today.

Mr. MORIN. OK.

Senator HARKIN. I can assure you of that.

Mr. MORIN. I appreciate that.

Senator HARKIN. And I will ask him to explain his actions on that phone call, and we are going to find out just what happened on that phone call and why he made it.

Mr. MORIN. OK. Well, I appreciate that.

Senator HARKIN. I am infuriated by it.

Mr. MORIN. Yes. I am infuriated by it, too, and I told other people, hoping that that would protect me from anything that they may try to do to us. Of course, that frightens me as a person that this agency would have the nerve to do that.

But, anyhow, what I would like to say is I understand people want to protect people from these things and we need to have research, but the things we are using are research and we as citizens can decide. As a parent, I look at all the side effects of anything we would use on my daughter and, believe me, the things that we use are a lot less harmful.

My daughter has been irreparably damaged by chemotherapy, which is approved by the FDA. For that matter, after we used it, I found out that this actually made her cancer more dangerous. To this day, the condition she is in right now is probably because of the chemotherapy that we used.

Senator HARKIN. Did you earlier—and I will refresh your memory—did you earlier say something to me that this person who called you—now, I know who it is, Dr. Jacobs.

Mr. MORIN. Right.

Senator HARKIN. Did he make some statement to you on the phone about his superiors at NIH?

Mr. MORIN. Correct, that they did not want him to—he had been trying to study Dr. Revici's medicine for a period of 2 years and they would not allow him to. When I asked him who that was, he wouldn't answer me, and I asked him if it was the pharmaceutical companies, which, you know, of course, came from my own personal opinion, and he would not answer me. As a matter of fact, he told me that if this conversation were brought up, he would deny it.

Senator HARKIN. Well, we will see——

Mr. MORIN. I guess what happened was people were actually calling him at his home, not just at his office.

Senator HARKIN. We will see if he denies it to me.

Mr. MORIN. OK.

Senator HARKIN. And if he does, maybe we will have to subpoena him and put him under oath. I will do the same to you, too.

Mr. MORIN. And I will welcome it. Thank you.

Senator HARKIN. Thank you very much. Go ahead and catch your plane. Thank you very much, Mr. Morin.

Mr. Schauss, do you have hard data on the number of deaths each year from drugs approved by FDA? You made some statements in here about two planes colliding in the air. Do you have some hard data on that and could you supply it to the committee?

Mr. SCHAUSS. Yes. Those reports come from the publications known as the Journal of the Medical Medicine Association and the New England Journal of Medicine. Each year, articles are written in both journals, and they have been since 1970, and it is very easy to glean all of that literature from just those two major medical journals. The data generally ranges between 80 to 120,000 deaths per year, and that varies according to the year.

Senator, could I just——

Senator HARKIN. Dr. Priestley, you—I am sorry.

Mr. SCHAUSS. Could I just say one other thing that was brought up? I want to point out that as a consumer organization we are equally concerned with this issue of safety, as has been expressed by the Consumers Union. But I think part of the equation that is missing here on the safety aspect is the fact that all licensed practitioners face malpractice if they make mistakes in their judgment, if they don't take time to research or understand their treatment, and that in many ways protects patients from being recklessly harmed, as some would contend.

In fact, every office of physicians I have seen who use alternative practices, the shelves are lined with textbooks. When you go into their file cabinets—I went in to one doctor's office and he had over 32,000 photocopies of papers that he had collected in 22 years examining these alternative treatments from all mainstream journals, all peer-reviewed journals.

So if they are going to that extent to read the literature before they apply an unconventional treatment, they are certainly taking into consideration their own risks as a professional in terms of their license and the care they deserve to give their patients.

Senator HARKIN. Well, Berkley, I just had the feeling in talking to FDA that we are two ships passing in the night; we are just not getting the same words together. I don't mean to imply that they are playing word games with me, but somehow we are not talking about the same thing. For example, the intended use doctrine that you brought up was not mentioned by FDA and I want to find out more about that in terms of "unsubstantiated" meaning "unapproved."

I think there are a lot of words here which I may not be fully cognizant of the import and meaning of those words as they are used by the Food and Drug Administration. I must tell you, and I say to those who are still here from FDA—is there anyone still here from FDA?

[A hand was raised in the audience.]

Senator HARKIN. I must say that I just got the distinct impression that FDA was sort of saying, well, there is no problem here, there is just not a problem. I just got that impression from them. Yet, from what I hear from consumers and a lot of other people, there is a problem. So, somehow, we have got to get our words

down to a level where we understand what we are talking about with each other here.

Ms. Odone, did you have something you wanted to add in this regard? Now, you are a medical doctor?

Ms. ODONE. No, I am most definitely not a medical doctor.

Senator HARKIN. Pardon?

Ms. ODONE. I have my degree in French and philosophy.

Senator HARKIN. Oh, French and philosophy. Is your husband a medical doctor?

Ms. ODONE. He has his degrees in law and economics. We were very motivated.

Senator HARKIN. So you did all this research and everything yourself?

Ms. ODONE. We had the benefit of all that Latin and Greek that all those nuns and priests made us take, yes. It was an easier start. We were very motivated by Lorenzo, who is doing quite well.

Senator HARKIN. Did you have any dealings with the National Institutes of Health during all this time?

Ms. ODONE. We availed ourselves of the National Library of Medicine for all of our research. We found it very convenient, but NIH had, in essence, delegated the study of ALD to another institution in Baltimore. There being so many rare disorders—ALD is no longer, by the way, considered a rare disorder, interestingly enough. I think the Odones' brouhaha for the last 10 years and the existence of the movie have brought out many, many cases worldwide. But at the time, there was a pretty sharp division of labor made, so that NIH was delegating ALD to an institution in Baltimore.

Senator HARKIN. Now, you are a consumer and you have heard this sort of dialogue going on in here about protecting consumers.

Ms. ODONE. Yes.

Senator HARKIN. Tell me, how do you feel about that? Is there a distinct danger for consumers?

Ms. ODONE. I feel uncomfortable being thought of as a consumer when someone's life is concerned. I feel comfortable, as the children say, being thought of as a citizen with freedom of choice. I would prefer not to be classified by the medical establishment or any other group as a nonphysician, and thus a member of the great unwashed who can't possibly understand anything, much less do research. I think that we nonphysicians are able to do research. We nonpharmaceutical companies are able to do research. I am not sure that the purity of research done by pharmaceutical interests is beyond reproach.

In terms of the FDA and its access and its trying to improve its process, I am sure that is great. There is the orphan drug mechanism now, but here the drug I was talking about in terms of beseeching its use in children with ALD, and certainly not under placebo-controlled trials, which is just immoral—beta interferon was approved as safe and effective by the FDA. Now, that should mean that it is widely available in this country to all of us consumers. It was also given orphan drug status by the FDA.

Now, I find two things rather amazing; first of all, that orphan drug status would be given to a pharmaceutical company who has developed a drug for MS patients. There are more than 200,000 MS

patients in this country. I don't think that was the intent of the law.

The FDA approval was granted so quickly, because it was so quickly obvious that the drug was safe and efficacious, that the manufacturer was caught with its suspenders down because it simply didn't have enough product for the consumer. I think someone should have been looking very carefully at the consumers' interests. So this drug has been available on a lottery basis. Now, there is something awfully un-American about that.

So our wanting to get this beta interferon for the children will not only involve our trying to educate parents about the fact that they needn't simply say, yes, doctor, yes, doctor, and hand them over as possible placebo receivers, but indeed we will have to be encouraging them to get beta interferon abroad because there isn't enough available here for the original population.

Senator HARKIN. Well, I have nothing else. Mr. Carolla, I have always had a great deal of respect and admiration for the Consumers Union. I am one of your great fans. I have always considered myself to be a strong consumer advocate in the Congress. I think my record shows that.

I have often thought that this legislation and other things along these lines are in the best interests of giving consumers a broader choice and more information. That is really what consumers need. I would hope that you and your organization would take another look at this bill in that light in terms of information and broadening choices.

To be sure, in terms of safety there may be some things that we could do in the bill. There may be some valid suggestions that can be made to tighten it up, and that is the process that we are involved in and I would hope that you would look at it in that light and give equal weight to the consumers in America for whom alternative therapies may hold great promise, but who are unable to get them because of the lengthy and costly process which they have to go through at the FDA, and give that equal weight in your consideration.

Mr. CAROLLA. Senator, when I first saw the bill my reaction was that I felt that in my heart I agreed with what you are trying to do. Then as I thought it through and parsed through different parts of it and talked to other colleagues on our staff who had, I think, some of the similar instincts, we found that this isn't the way to do it.

We did try in my testimony to suggest either alternative routes, if I may, or at least to try to offer some constructive criticism. We, in any case, regardless, would look forward to continuing to work with you on those interests.

Senator HARKIN. Well, I look forward to working with you on it, too. I think we can find some common ground.

Mr. CAROLLA. OK.

Senator HARKIN. Well, thank you all very much for being here. We must move on to our last panel. I do want to get to Dr. Schurholz. Thank you all very much.

Senator HARKIN. Dr. Jurgen Schurholz, M.D., chairman of the German Commission on Anthroposophic Medicine, and Michael Janson, M.D., vice president of the American Preventive Medical

Association from Cambridge, MA. It is good to see you again. Well, thank you again for being here—I would say this morning, but I guess it is this afternoon.

Dr. Schurholz, I have read your testimony; I did last night. I appreciate that. You heard Senator Daschle say, if you had some time this afternoon, he would like to visit with you personally. I hope that you do find the time to do that.

We welcome you here. Your statements will be made a part of the record in their entirety.

Dr. SCHARFF. I am Dr. Scharff, a physician. If there are translation problems, I will try to be of help.

Senator HARKIN. Thank you. I am sorry. Dr.——

Dr. SCHARFF. Dr. Paul Scharff, S-c-h-a-r-f-f-, M.D.

Senator HARKIN. Thank you, Dr. Scharff.

Dr. SCHARFF. I am in the same stream of therapy as Dr. Schurholz.

Senator HARKIN. I understand.

Dr. Schurholz, welcome, and please proceed.

STATEMENTS OF DR. JURGEN SCHURHOLZ, CHAIRMAN, GERMAN COMMISSION ON ANTHROPOSOPHIC MEDICINE, BERLIN, GERMANY, ACCOMPANIED BY DR. PAUL W. SCHARFF, FELLOWSHIP COMMUNITY ASSOCIATES, SPRING VALLEY, NY; AND DR. MICHAEL JANSON, VICE PRESIDENT, AMERICAN PREVENTIVE MEDICAL ASSOCIATION, CAMBRIDGE, MA

Dr. SCHURHOLZ. Mr. Chairman, thank you. My name is Jurgen Schurholz, M.D., and I am an internist and physician graduate of the University of Hamburg School of Medicine. Since 1978, I have served as the chairman of the Federal Health Agency Commission C for Anthroposophic Therapeutic Line and Their Remedies in the Bundesgesundheitsamt in Berlin. The C Commission evaluates the safety and efficacy of therapies and remedies. Now, what is anthroposophic medicine? It takes into consideration the physical, the physiological, and spiritual and mental realm of the patient.

For the past 18 years, I have also served as the chief of service of the Filder Clinic, a 260-bed community hospital near Stuttgart. At this hospital, we practice a wide range of treatments which are unconventional. Last year, I retired from my position at the hospital to dedicate my time to the study of various natural remedies of clinical interest.

In Germany, there is, as you know, a long history and tradition associated with the use of natural therapies, and Germany took this into consideration when it passed the medication law of 1978 to provide a regulatory framework of legalizing alternative remedies. At the time this bill was being debated in our congress, critics made all kinds of unsupportable claims that the public would suffer harm or fail to use effective conventional therapies. After more than 15 years of experience, these criticisms have proven to be wrong.

The medication law of 1978 was also important in that the government decided to acknowledge the following. First, freedom in one's choice of therapy by the doctor and the right of self-determination by the patient should be guaranteed. Second, the existence and equal justification of various lines of therapeutics should

be expressly recognized. And, third, health authorities are obliged to take into consideration the State of scientific knowledge of each line of therapy or different schools of medicine when advising the public or practitioners about their benefits.

In addition, it was also agreed upon that in all matters of medical treatment it was ultimately the obligation of each physician to listen to his conscience when considering treatment for his patients. However, he must also be able to give plausible reasons for his choice of treatment to his patients by being informed of the merits and risks associated with any treatment he may elect to use. This is where the commission's monographs on such remedies prove to be invaluable guides for the practitioner.

Through the work of three special commissions, of which I have chaired one 16 years, Germany's medication law put anthroposophic medicine, which is studied by Commission C, homeopathy and phytotherapy, which are studied by Commissions D and E, on an equal footing with those remedies of modern pharmacology referred to as drugs.

One of the functions of these commissions within their peer review and authority is to evaluate the efficacy and safety of traditional and unconventional remedies and therapies by evaluating data from clinical trials, field studies, case histories, and a careful review of the scientific literature. Information is sought from all sources, including medical associations, specialists, and standard reference works. When this process is completed, monographs are issued by our commissions and published in the German Federal Gazette, the equivalent of your Federal Register.

In Germany, physicians can acquire additional training in fields such as homeopathy or naturopathy. This enables patients to visit doctors who have a different perspective or understanding of health and the treatment of disease from that practiced by drug-use-oriented physicians. We have already heard this morning that since January 1993, all German medical students must show in their final examinations their knowledge of the use of phytomedicines, an inevitable consequence of the growing demand by the public for physicians' knowledge of botanical medicine and in recognition of the considerable scientific basis for its use in the prevention and treatment of disease.

It is not a secret that a segment of physicians and some medical associations and university faculty still continue to resist these efforts at creating a more pluralistic system of health care. However, as these alternatives are being repeatedly demonstrated to be safe, efficacious and cost-effective, day after day and year after year, one has to begin to question the motivation of those critics who wish to return to the old days when doctors dared not practice alternative medicine and patients felt intimidated from seeking such alternatives.

The realization that numerous alternative or unconventional therapies can help patients has led to other developments in Germany that should be of interest to those working to expand access to alternative therapies in the United States.

A number of universities in Germany are encouraging faculty to direct their knowledge and experience into the study of alternative medicines. Additionally, an official expert group on unconventional

cancer therapies has been raised and funded by the government. These are just two examples of change that are occurring as a result of our government opening the door to increased access to alternative health care through Federal legislation.

It is also important to point out that 90 percent of German citizens today can receive reimbursement of alternative remedies through their insurance providers. This was accomplished after two laws that were passed in 1989 and 1993 by our Federal government legalized these reimbursements for alternative treatments and remedies approved by our commissions.

Also, today all health insurance companies must cover a broad range of unconventional remedies not only because of their cost savings to the company, but also because they are beneficial to patients. A survey conducted 5 years ago reported that 60 percent of mainstream physicians prescribe remedies which we would classify as alternative, and 58 percent of consumers reported that they believed it is important to keep alternative remedies and treatments available. My opinion is that these figures are much higher today.

As a prime example of the growing acceptance of alternative health care in Germany, I was pleased to learn recently that the State in which I live, Baden-Wuertemberg, awarded 40 million deutschmarks, about US$30 million, to my community hospital to increase space for patients receiving such care.

In summary, as a result of legislation passed in 1978, pluralistic medicine has become legally available to everyone living in Germany. There are no essential prohibitions of any kind to any treatment, and there are no malpractice problems with alternative medicine. Those who predicted in the 1970's that the public would be harmed or that they would fail to seek effective conventional treatments have been proven wrong.

I want to commend your Congress for taking steps to ensure that Americans may have the same rights of access to alternative health care that Germans have experienced for many years. Although this may mean fewer Americans coming to our country to seek alternative therapies, we should remember that we are all part of the same healing community.

I want to thank this Senate committee for inviting me to testify at this hearing, and I was able to learn this morning, and I am very impressed, how you stand for the individual. Thank you.

Senator HARKIN. Thank you very much, Dr. Schurholz. Just as we don't want to reinvent the wheel again in remedies and therapies that have been used for many years—I mentioned that earlier—I don't think those of us in Government ought to try to reinvent the wheel in terms of legislation. So what I want to do is to get a copy of the legislation that you passed and any supporting documents, perhaps comments, that type of thing, surrounding it. I think we ought to take a look at it. It might provide us with some basis for modifying the bill that we initially have put in here. So I will have my staff work with you and perhaps you can help get us that type of information as to how that legislation is drafted and how it was implemented, and that type of thing. I would appreciate that very much.

I will be back. I have a couple of other questions, but I wanted to make sure I didn't forget that.

[The prepared statement of Dr. Schurholz may be found in the appendix.]

Senator HARKIN. Now, we will turn to Michael Janson. Dr. Janson, again, welcome to the committee. It is good to see you again, and please proceed.

Dr. JANSON. Thank you. My name is Michael Janson and I am a physician in Massachusetts, and I must say I subscribe to Consumer Reports, but not to all of their positions, especially on health care, and part of the reason for that is, as I have read it over the years, my opinion has been that their health advisers are strongly biased against alternatives in medicine and anything other than strict, mainstream care.

I am here today as the vice president of the American Preventive Medical Association, which was founded 2 years ago as an advocacy organization for physicians who have been using nutritional, preventive, and other innovative therapies with hundreds of thousands of patients for decades.

APMA physicians all completed medical school and have expanded on what we learned there, believing that there are better ways to deliver safe, effective, and affordable health care. We seek not to discard the enormous benefits of mainstream medicine, but to enhance them. Our practices have been called alternative or holistic, complementary, preventive, but really we call it simply good medicine.

Although the APMA advocates mainstream medical treatments when appropriate, we are also aware of many effective and safe therapies and diagnostic techniques involved diet, nutritional supplements, chelation therapy, stress management, acupuncture, and herbal remedies, among many others. Frankly, if mainstream medicine were working so well, people wouldn't be seeking alternatives.

There is a lot of research to support most innovative treatments. The fact that they are not widely accepted is due more to inertia and resistance to change than to science. Further research is greatly needed. It is always needed, but the fact is if no treatment were ever initiated without conclusive research, there would be little medical treatment at all of any sort.

Most importantly, too few physicians will acknowledge or offer these treatments due to fear of professional persecution or ridicule. I myself have decided not to do certain therapies because I am afraid of the political implications. That doesn't mean I don't do many of them.

There is a real public health danger—and I cite consumer safety—there is also a real public health danger from preventing doctors from pursuing advancements in medicine and restricting access to a variety of therapeutic options that licensed professionals would like to administer and patients would like to receive. There is some atmosphere out there that consumers are ignorant and that they are not willing to look into all the risks and benefits; that there is not enough information and they can't evaluate what is available. That is really a myth.

The fact is patients are very aware, and the ones that aren't aware don't seek these sorts of treatments, but the ones who do seek them are aware and need to have the right to make those evaluations for themselves. In fact, the problem that brings us here

today was recently summarized in a single sentence by a patient who said, nowadays when you get a chronic disease, you don't call your doctor, you call your travel agent. It is a very frustrating situation.

Limited access to health care choices, persecution of doctors who are doing no harm, restricting education and information about treatment choices, and forcing patients to choose between drugs, surgery, or travel abroad is neither humane nor consistent with American values. Yet, professional licensing boards, insurance companies, and government agencies are increasing their efforts to harass, intimidate, and even revoke the licenses of physicians offering these treatments.

When the FDA says that they don't go after doctors unless they are doing something that hasn't harmed their patients but might harm other patients from their information, they also attack doctors for using diagnostic equipment which is perfectly harmless and there is no evidence or reason to suspect it might do harm, but they are using an unapproved piece of diagnostic equipment.

One of the arguments against wider choice in health care is that ignorant or misguided patients who choose alternatives will be led to ineffective or dangerous treatments, and therefore miss out on the wonderful results from traditional medical care. Rarely is any evidence offered to support this concern. In addition, traditional medicine is often ineffective and dangerous, even things approved by the FDA.

Now, I am going to submit for the record something that is not in my testimony. It is this little article that was a report from the GAO, the General Accounting Office, in 1989 after 14 years of treatment on chemotherapy as a treatment for breast cancer. Chemotherapy for breast cancer is a devastating treatment. It doesn't kill everybody who gets it, but it does harm everybody in some way.

According to the U.S. General Accounting Office, the therapy has demonstrated no measurable impact on survival during the last 14 years. So all the expense, all the side effects, the loss of hair, the digestive disturbances, the fear, and the general debilitation that chemotherapy offers didn't, during the 14 years that this was carried out, with all of the FDA approval, have any impact on survival. So when we talk about effective treatments from the FDA's approval system, it is not really an accurate picture.

[The document referred to may be found in the appendix.]

Dr. JANSON. In many cases, alternative medicine is simply better medicine. Alternative treatments are not necessarily in conjunction with mainstream treatments. They can be instead of, and I can use examples which I will submit also in another chart that I made up, just my ideas about comparing treatment options for heart disease, hypertension, allergies and asthma, and prostate enlargement—traditional versus nontraditional treatments.

[The chart referred to may be found in the appendix.]

Dr. JANSON. APMA physicians do not ignore mainstream treatments, but we do use alternative therapies when we expect them to be safer and more effective. We often use these treatments in conjunction with mainstream treatments, and patients frequently seek both types of therapy, contrary to the charges of many critics.

Innovative doctors, I hope, like myself, do not prey on the poor and uneducated, the people that are supposedly so ignorant that they can't make a value judgment for themselves. The fact is studies show that more affluent and better-educated people are the ones who most often seek this kind of care. I would like to see it more accessible to the people who are less educated and less well-off.

There is an unfounded accusation, also, that our practices are not based on scientific data, and that is really absurd. Most of the things we do have either extensive or suggestive scientific evidence that is showing that it is safe and may be effective, and in some cases clearly effective. Some of them are clearly effective more so than the treatments that the FDA has approved.

I talked to you earlier in a previous hearing about prostate enlargement and the herbal remedy which the FDA's own reports show is statistically better than the drug that they approved for the process, but they refused to allow a claim for the herb.

What we do is really based on science, but the fact is even in mainstream medicine, both the Government General Accounting Office and a former editor of the New England Journal of Medicine said that 85 percent of medicine practiced today is not based on adequate scientific data. This is not to say that those practices are bad, but it is to point out that medicine is really an art as well as a science, and doctors have to have some leeway in that.

Medicine is not a static science, but stifling innovation will make it one. It will eliminate advances in medicine in a misguided effort to protect consumers from imagined dangers. Doctors should not be punished for pursuing their craft in the absence of harm to patients, particularly when patients find that the treatments offer a better quality of life and they are more affordable.

Since patients are rarely the initiators of harassment, the record of suppression suggests that patient welfare is not the real motive. My personal opinion is that consumer protection is not the real issue here. Most people are not being harmed by alternative medical treatments. That is not to say we don't have to be aware of and constantly on the lookout for potential problems.

It really is unfortunate indeed to have less choice in health care in America for both the doctors and the patients than is found in England, France, Germany—and I commend the German government for its open-minded position—and, of course, almost any other country. Doctors really need to have the freedom to discuss and provide all forms of treatment with their patients, and the patients need to be able to make informed decisions about mainstream and innovative treatments. They need to know the benefits and risks of alternatives to the level of our knowledge of them, and also the risks and the benefits of avoiding mainstream care.

We have an assumption that if people avoid mainstream care, they are taking a risk. But, in fact, there may be a benefit to avoiding mainstream care, as I pointed out with chemotherapy, and I could tell you more, if we have some time, about bypass surgery and other things that are quite accepted and approved. The real issue is not safety. I have been doing this for 18 years and I can tell you that, compared to other medical practices, that is not the issue.

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APMA doctors have no interest in therapies that might harm their patients, nor do their patients wish to have government dictate their treatment options. We need to trust in the doctor-patient relationship, but also to pursue those who abuse this trust. Practitioners who do harm are at least as likely to come from the so-called mainstream.

Without the passage of this bill, professionals will continue to be intimidated into avoiding innovative forms of care, and this will stifle the development of new treatments. It must be remembered that hand-washing, antisepsis, and even antibiotics were all fringe therapies at one time.

In my medical practice in Massachusetts over the past 18 years, I have seen over 10,000 patients, and it is clear that many people are willing and competent to make their own choices regarding health care. They are not being duped, nor are they being put in danger. APMA doctors who care for them are well aware of the professional risks that they take because they are innovative. They continue because they feel it is the best path for their patients and it is responsible health care.

The APMA membership wants Congress to foster advancement and innovation in medicine through passage of the Access to Medical Treatment Act, which we strongly support.

Thank you.

[The prepared statement of Dr. Janson may be found in the appendix.]

Senator HARKIN. Dr. Janson, thank you very much for your very fine testimony and for your leadership nationwide in this effort.

Dr. JANSON. Thank you.

Senator HARKIN. I appreciate your support of the bill, and again I encourage you and your organization that if you have constructive comments on the bill that need to be changed and modified, please let us know.

Dr. JANSON. Sure.

Senator HARKIN. I just might add again for the record and for the benefit of the people who are here today that while I agree with Senator Daschle that this is the beginning and I don't know how long the process will take, I would like to see some effort in this regard made on health care reform. Assuming that we pass some form of health care reform in America in the next month here, I would like to see at least an opening made in this area so that we can begin to expand this use of alternative therapies and provide for more consumer choice in health care.

If we are going to do health care reform, it seems to me this is a very important part of health care reform. One of the reasons we wanted to hold the hearing today was to get this information in prior to the health reform bill coming before the Congress, and that is why I intend to use the statements here and what has happened in Germany and your association, Dr. Janson, the American Preventive Medical Association, and others to build a basis for, if not the complete bill that we have, at least some version of that to open the door in health care reform.

Dr. JANSON. What your bill is doing is real health care reform because it is reforming the care for the patient. The other bills that are being discussed are bills about delivery of care and financing

of care. They are really not health care reform, they are delivery reform, and I think both are important.

Senator HARKIN. That is true; a good point. I appreciate that. That is true.

Dr. JANSON. Thank you.

Senator HARKIN. I have said many times if all we are going to do is just rearrange how we pay and who pays and how it is delivered, we are just rearranging the deck chairs on the Titanic. We are still going down. We need more preventive care and more knowledge about different processes and therapies that can keep people healthy in the first place.

Dr. Schurholz, this Federal health commission that you sit on in Germany—what sources of information do you use to evaluate treatments?

Dr. SCHURHOLZ. As I tried to point out, there are several opportunities to find this. There are for our group only very little clinical trials, none really which the FDA would accept, as such. I go on, but let me say a few words at this point. We heard this morning the dogma of the proved remedies, and we heard the example of the white mice the patients are put in if the doctors used not proven remedies.

Now, what is a trial? It is to find out if the remedy works, and we always have two groups, such of responders and such of nonresponders. If the group of the responders is a little bigger than the group of nonresponders, it is proved, and it is positively proved. Now, if I have my patient across from me on his chair, I never know to which he belongs, and even if I give him a beta blocker, which is a proved remedy, I don't know how he will behave when he has high blood pressure on this drug. I have to try every time, and this is not a question of alternative medicine. This is a question of medicine as such that the doctor has to do so.

Senator HARKIN. Let me put it in layman's terms. What you have just said is that earlier today we heard from the FDA, who said that if we allow practitioners to give unapproved medicines to patients, then they are becoming white mice; the patients are then treated as white mice. What you are saying is that even if you use an approved medicine and you give it to an individual, you don't know specifically how that individual may react to that specific medicine that has been approved. You have no way of knowing that.

Dr. SCHURHOLZ. Exactly.

Senator HARKIN. All you know is that in the earlier trials, more had a positive reaction than had a negative reaction.

Dr. SCHURHOLZ. Right.

Senator HARKIN. And you don't know to which group your patient falls.

Dr. SCHURHOLZ. Right.

Senator HARKIN. So, in a way, every patient is a white mouse.

Dr. SCHURHOLZ. You can't get rid of this problem.

Senator HARKIN. That is true, so you might as well give the white mouse all the information that that white mouse can use to make an informed decision as to which medicine that white mouse wants to take. I like it. I wish I had put you on first. [Laughter.]

Dr. SCHURHOLZ. If I may——

Senator HARKIN. I should have put you on first. That is very good. I am sorry. Go ahead.

Dr. SCHURHOLZ. What Dr. Michael Janson pointed out—you see, science can't be the goal of medicine. Science just can be a basic tool, but we have other tools as well. It was spoken about the relationship between the doctor and the patient. Knowledge is needed by the doctor, knowledge about remedies, but knowledge about the patient—as you pointed out this morning, how do you sleep, how do you feel, how do you manage this and that—knowledge about and kind of a picture of the patient so that the doctor gets a real concrete approach to this person. That is a tool.

Last but not least, he needs experience and he needs, really—we heard that already—he needs to be motivated and he needs his will to help or to heal. These are the tools a doctor necessarily has to handle, and science is the basic one, but not the only one, and we can't sacrifice medicine to science. [Applause.]

Senator HARKIN. That is very good. I tried to write all that down.

Dr. SCHARFF. Maybe one could mention that there might be different sciences, and that is something that some of us are very concerned with. They have now had some first exchange at the Office of Alternative Medicine, but that is a real issue to be taken up. We have to be careful. When somebody says "science," there are different forms of science, and that is a very difficult tool to look at.

Senator HARKIN. Yes, and I think that in medicine today—I am going out on a limb on this one—I think that in medicine today, as these people go through medical school, I am not saying they are taught to be numb to patients. That is not so. I think they are sort of taught, as someone said earlier—I don't know who it was that said they take about 2,000 hours studying different drugs. They are taught to always look for the silver bullet. You know, if someone comes in, you analyze them and you give them a drug and out the door they go.

Eventually, we will all be able to have a Salk polio vaccine. We will all be able to take something that will cure us of whatever it is that we have. But as you said, medicine is not a science, it is an art. It is not static, it evolves. Illnesses are not static; they evolve, also. We have different illnesses that affect us today than affected us 100 years ago or 1,000 years ago, and we will have different illnesses in the future because the human body and human interactions change and evolve. We never had AIDS before. It is something new, and so we have to understand new ways of dealing with these illnesses.

So I think that you really put your finger on it. You talked about the German medical students on their final exam having a knowledge of phytomedicines. I had to ask what that meant, the study of plant medicines and plants. They have to understand that. I don't know. I would ask Dr. Janson. I don't think that is true in America, is it?

Dr. JANSON. No, it is absolutely not true. I mean, there are a few natural products that are in use and we study them, and they happen to be herbs; digitalis, for example. That is one of the rare herbal medicines. There are some. In previous testimony in the previous hearings that we had, the FDA testified about how many drugs are derived from herbs, but that was sort of a specious argu-

ment. They are so far removed from herbs that they no longer qualify as herbal remedies. They are really drugs, so we get no training other than the traditional few in herbal remedies. I didn't learn anything about garlic, for example, in medical school. We are now seeing it in Newsweek and Time Magazine, but we didn't learn it in medical school.

Senator HARKIN. Dr. Schurholz, to follow up, I talked about your sources of information and how you evaluate. How do you disseminate to doctors, health practitioners, around Germany so they can decide which treatment they should use with a patient? How is that disseminated? Do you have in Germany the equivalent of an FDA like we have here?

Dr. SCHURHOLZ. Yes.

Senator HARKIN. You do have that?

Dr. SCHURHOLZ. Yes, sure, our Bundesgesundheitsamt, BGA.

Senator HARKIN. So how do you get this information out to doctors from your Federal health commission?

Dr. SCHURHOLZ. Well, we just ask them. We know the doctors. For instance, for this anthroposophic medicine, we know about 800 doctors who are experts on this line of medicine and we send a letter to them and ask them about their experiences with such-and-such drug, and we work that out scientifically in order to have this for our monographs, as well as, as I pointed out, the standard reference works and the scientific literature and our own experience, of course, at the commission. How doctors are referred to—it is by the Federal Gazette.

Senator HARKIN. You publish it in the Federal Gazette?

Dr. SCHURHOLZ. We publish it, yes, and before we publish it in the Gazette we publish it in medical journals. That is the pre-published——

Dr. SCHARFF. It is published in medical literature. Every line, every mode of therapy has its own literature, and there knowledges are disseminated and that is how that is done. It is a fairly well-informed group of people.

Dr. SCHURHOLZ. I put my finger on the conscience the doctor has listened to when he treats his patient, so he certainly should just use remedies he knows. The needles we heard of this morning don't do anything but hurt and make the skin bleed if you don't know how to handle them. So you have to know how to use these remedies, and this is left to the doctor, as such. As I pointed out, there are no treatments prohibited in Germany.

Senator HARKIN. OK. Can I stop you right there?

Dr. SCHURHOLZ. Yes.

Senator HARKIN. There are no treatments prohibited?

Dr. SCHURHOLZ. No.

Senator HARKIN. One of the things we keep hearing about this legislation is that patients will be exposed to harmful and dangerous treatments. Have you found that this expanded access has resulted in an increased number of negative reactions to treatments? What has your experience been? Has the number of negative reactions gone up?

Dr. SCHURHOLZ. No.

Senator HARKIN. How do you prevent——

Dr. SCHURHOLZ. This morning, we heard about chemotherapy. That is dangerous, isn't it?

Senator HARKIN. Yes.

Dr. SCHURHOLZ. It is proved and it is dangerous. We hardly have any remedy which is as dangerous as chemotherapy, so it depends on the knowledge and the experience of the doctor weighing up the risk.

Senator HARKIN. I have a vote on the floor, darn it, that I have got to go make, but how do you also answer the question that if we do this, it will open up the door to charlatans? I don't know how you translate that into German, but quacks, people who prey upon sick people and say, oh, here is the cure for you and you can use that. How do you answer that question?

Dr. SCHURHOLZ. Well, to be honest, you can't even in mainstream medicine. There are charlatans in mainstream medicine, aren't there?

Senator HARKIN. That is true.

Dr. SCHURHOLZ. Yes, and you can't get rid of them.

Dr. JANSON. But, luckily, people in alternative medicine—the percentages may not be any different, but they are using much safer treatments. When you talk about bypass surgery, which has no real evidence to recommend it for 70 percent of the people who get it, or balloon angioplasty—I was just speaking with Tom Graybois of the cardiovascular group at the Brigham Hospital. He said we have no data that suggests that angioplasty, or the balloon in the arteries, is of any value to patients to extend their life span. Yet, these devices for medical treatment are approved by the FDA; no evidence that they are effective, and they are certainly not safe. Even though the percentages are small, if it is you, it is 100 percent.

So there is no question that you are going to have fewer side effects by doing less medical treatment for conditions that don't benefit from mainstream medical treatment.

Senator HARKIN. Dr. Schurholz?

Dr. SCHURHOLZ. Again, to your question, you know, this dogma about the harmful remedies—this is just relative thinking because there is no efficacy, so any risk is too high. This is just to be accepted. If you accept that there is no efficacy, then you can speak of the harmfulness of the remedy, but as soon as you are convinced by your experience that you have efficacy, then you can take the risk. It belongs to the being of a remedy to be somehow poisonous. It is a question of the doses.

Senator HARKIN. I don't understand that. You have lost me on that.

Dr. SCHURHOLZ. I am sorry.

Dr. SCHARFF. Most therapeutic agents have inherent in them a poison quality. That is why you have adverse actions.

Senator HARKIN. I see.

Dr. SCHARFF. If you know what those adverse reactions—you know how to handle it; you can minimize such an adverse reaction, and that is true of all therapeutics.

Dr. JANSON. Even nontherapeutics. You can get toxic from too much water. There is water intoxication if you drink too much.

Pathological reasons, whatever it is—anything in enough of a dose can be harmful.

Senator HARKIN. I see what you are saying.

Dr. JANSON. But the range of therapeutic effectiveness compared to the dose that you need to have harm is so much greater in almost all dietary supplements, phtyochemicals, and acupuncture. I mean, acupuncture itself—you can't find harm. Of course, there is the potential of contaminated needles, but people are using disposable needles now. I was delighted to find out that the FDA approved shipping them across State lines as long as they are labeled for selling.

Senator HARKIN. Basically, yes, that is true. They just have to be labeled "needles." If they are just needles, that is all, I guess.

Well, I only have about 5 minutes left on this vote now. I congratulate what you have done in Germany. That is a great step forward. I think we have a lot we can learn from you and I want to get as much information as I can from you and from Germany, and if you would be so kind as to—I am going to run out of here in a mad dash to make a vote. If you would let my staff know to whom we can write or how we get a hold of this information, and perhaps even if it is translated into English, obviously that would be a great help, so that we might use that here, also.

Did you have something?

Dr. SCHARFF. I just wanted to make one remark. I have been in this business for 35 years. My experience is the alternative therapist has much less in the way of malpractice than regular medicine, and that should be looked into.

Senator HARKIN. I accept that.

Dr. JANSON. I think that the——

Senator HARKIN. I just have to leave. I am going to be late for this vote; I am going to miss it.

Dr. JANSON. Go. I will talk to you later.

Senator HARKIN. I am going to keep the record open for 2 weeks for anyone who was not called as a witness who wanted to submit some testimony or those who did testify to submit additional evidence or statements in the record. I will keep it open for 2 weeks.

Again, I just thank you all more than I can ever express for being here this morning, traveling a long distance. For all of you who may be in the audience who are involved in alternative medicine, I thank you very much for being in the forefront of expanding our choices and being really, I think, on the side of consumers in this country.

We are going to move this legislation in some way. I am going to try to figure out some way that we can get it involved in our health care reform bill coming through the Congress here very shortly. We may not get 100 percent, but we will get something in there that will open the door. [Applause.]

Dr. JANSON. Thank you, Senator Harkin.

Senator HARKIN. So, again, the committee will stand in recess. Again, I just thank you more than I can say. Thank you all very, very much.

[The appendix follows.]

APPENDIX

PREPARED STATEMENT OF MARY K. PENDERGAST

Mr. Chairman:

We are here today to discuss with you S. 2140, the "Access to Medical Treatment Act."

INTRODUCTION

Let me start by emphasizing that the Food and Drug Administration (FDA) is committed to providing early access to potentially useful medical treatments to patients who might otherwise have no hope. In my testimony I will describe the mechanisms we have put into place to make promising investigational new drugs and medical devices available as early in the developmental process as possible without jeopardizing the safety of very ill, and vulnerable, patients. I also will describe the efforts we have made to streamline our regulations and operating procedures to speed the approval of important new drugs and devices. I will describe the grants and other efforts our orphan products program has made to support the researchers who are testing drugs and medical devices that have not been supported by the large manufacturers. And I will advise you of the significant concerns the FDA has with S. 2140.

But first, I think it is useful to explain briefly what the current statutory scheme for the testing and approval of drugs, devices, and other medical products.

CURRENT STATUTORY SCHEME

FDA's original law, the Food and Drugs Act of 1906, was passed by Congress as a result of unhygienic conditions in Chicago's meat-

packing plants. The law, however, did little to control the use of dangerous and fraudulent drugs and devices. While weaknesses in the law had been discussed and debated for years, it took a catastrophic incident to propel further action. In 1937, more than 100 people, almost all of them children, in 15 states died as a result of taking a liquid dosage form of the drug sulfanilamide. This new liquid formulation, Elixir Sulfanilamide, contained diethylene glycol (used as antifreeze) and was marketed without benefit of any toxicity testing, since at the time the law did not require safety studies on new drugs. The Elixir of Sulfanilamide scandal followed closely on the heels of another tragedy. In the 1930's another drug, dinitrophenol, widely used for weight reduction, resulted in deaths, as well as hundreds of cases of blindness, agranulocytosis (a potentially fatal blood disorder), and other serious adverse reactions.

These incidents hastened the enactment of the Federal Food, Drug, and Cosmetic Act in 1938 and considerably expanded consumer protection by requiring safety testing of new drugs prior to approval for marketing. In short, in 1938 Congress told companies that they had to test their drugs for safety and submit an application to FDA, before a drug could be approved for marketing. Because of this law, products such as thalidomide (which caused phocomelia, a severe limb deformity in exposed fetuses) were not marketed in the United States and, consequently, the public was spared enormous suffering.

In 1962, Congress set in place the second cornerstone for our public health and consumer protection efforts. Congress stated that before a company could sell its drug to patients, the company had to test the drug and show that it was both safe and effective. Effectiveness had to be shown through adequate and well-controlled clinical trials, which represented the scientific standard for evidence in 1962, and still does today. In 1976,

Congress again amended the law to establish a regulatory scheme designed to help ensure that medical devices also would be safe and effective.

TESTING AND REVIEW SYSTEM

Let me now describe the drug and device testing and review systems currently in place. I want to stress that FDA does not care whether a product is characterized as "mainstream" or "alternative;" we do not care whether the product was synthesized in a state-of-the-art laboratory or was found in the Brazilian rain forest. We care that the product is studied scientifically in properly controlled trials, so that we can know whether it works for a specific purpose and so that patients are not exposed to experimental products of no proven value. The scientific process I will describe works for all of these products.

NEW DRUG REVIEW PROCESS

A new drug may not be distributed in interstate commerce (except for clinical study) until a sponsor, usually the drug manufacturer, has submitted, and FDA has approved, a New Drug Application (NDA) for the drug. For approval, the NDA must contain substantial scientific evidence of both the safety and effectiveness of the drug for its intended uses.

For a drug that has never been used before, the first step a sponsor must take is to test the drug in animals for toxicity. The sponsor then takes that animal testing data, along with additional information such as the drug's composition, manufacturing, and control data, and develops a plan for testing the drug in humans. The sponsor submits these data, along with its study plan, the qualifications of the investigators who will conduct the studies, and assurances of informed consent and

protection of the rights and safety of the human subjects, to FDA in the form of an Investigational New Drug (IND) application. FDA reviews the IND and makes sure that the animal tests do not show that human subjects might be exposed to unreasonable risk of harm. At that point, the first safety studies of the drug can take place in humans -- usually healthy volunteers. These initial safety studies are called "Phase 1" studies. Phase 1 studies carefully assess the safety of the drug with an emphasis on evaluation of the toxic manifestations of the therapy, how the body distributes and degrades the drug, and side effects associated with varying doses. Phase 1 often includes fewer than 100 normal volunteers or patients.

As clinical studies become more extensive and longer in duration, other animal studies are carried out, including studies of reproductive effects, effects on the fetus, and chronic studies, so that the safety of the further human studies can be assured as much as possible. Phase 2 clinical studies consist of the first controlled clinical studies in patients with the disease to be treated to evaluate the effectiveness of the drug for a particular indication and to determine common short-term side effects. Phase 2 studies typically involve a few hundred patients. It is important to realize that 80 percent of all drugs tested are abandoned by their sponsors after either Phase 1 or 2 because of excessive toxicity or inadequate benefit.

Once Phase 2 studies are successfully completed, the drug's sponsor has learned much about the drug's safety and effectiveness. At this point, larger controlled and uncontrolled studies, called Phase 3 studies, involving several thousand patients can be conducted. These studies can examine additional uses, obtain further safety data including long-term experience, and consider additional population subsets, dose response, etc. FDA strongly encourages sponsors to work closely with the agency

in planning definitive Phase 3 clinical trials so as to ensure adequacy of clinical trial design.

Once Phase 3 testing is completed, the sponsor submits the test results to FDA in the form of a New Drug Application (NDA). FDA's medical officers, chemists, statisticians, and pharmacologists review the application to determine if the sponsor's data in fact show that the drug is both safe and effective. The manufacturing facility is evaluated to ensure that the product can be produced with high quality. Finally, safety and effectiveness data may also be audited by FDA through on-site inspections to verify that complete and truthful information has been provided in the application.

The testing of a biologic is done the same way as for drugs, except that the final application is called a "Product License Application" (PLA) and not an NDA.

MEDICAL DEVICE REVIEW PROCESS

Medical devices include tens of thousands of health products, from simple articles such as thermometers, tongue depressors, and heating pads, to sensitive and complex devices such as cardiac pacemakers, magnetic resonance imagery equipment (MRI), and kidney dialysis machines. Prior to 1976, no specific federal statutory program existed to regulate medical devices. The increasing sophistication and complexity of medical devices, coupled with a growing number of safety concerns, helped forge a consensus that these products should be regulated by the federal government. This led to enactment of the Medical Device Amendments of 1976, which gave FDA specific authority to regulate the safety and effectiveness of medical devices.

The 1976 law provided several mechanisms to achieve this goal, including classification of medical devices, device listing,

establishment registration, adherence to Good Manufacturing Practices (GMPs), and scientific and clinical evaluation of new devices before they are commercially marketed. The Safe Medical Devices Act of 1990 (SMDA) and the Medical Device Amendments of 1992 expanded our regulatory authority and responsibility.

In general, the Medical Device Amendments of 1976 created two pathways a manufacturer could follow to legally market a medical device: 1) premarket notification, known as a "510(k)"; and 2) premarket approval application (PMA). Devices in commercial use prior to 1976 were legally allowed to remain on the market. FDA intends, over time, to require PMA's for all pre-amendment implantable and life-supporting or life-sustaining devices. All devices marketed subsequent to the 1976 amendments require clearance or approval through one of the two mechanisms just described.

Under the 510(k) process, FDA must determine whether a device is "substantially equivalent" to a legally marketed device. A company must submit an application with information that will enable the agency to make that determination. If the new device is found to be substantially equivalent to a legally marketed device, the company can then market the product.

In general, implantable and life-supporting new devices that are not substantially equivalent to a pre-1976 device require the submission of a PMA. A PMA is similar to the NDA required for new drug approvals. A PMA must demonstrate a reasonable assurance that the device is safe and effective under the conditions of use in the labeling. PMA submissions typically are very complex and include the results from clinical testing. Such testing is generally conducted under an Investigational Device Exemption (IDE), similar to an IND for drugs. An IDE generally is necessary to permit a company to introduce an investigational

device into interstate commerce for the purpose of testing the device in human clinical studies.

EFFORTS TO EXPAND ACCESS TO UNAPPROVED PRODUCTS

In recent years, FDA has reexamined the product development and review processes to identify ways to expand access to promising therapeutic agents without compromising the thoroughness and scientific integrity of the development or review, or the protection afforded to human subjects. Regulations and guidelines have been promulgated to define how and when a breakthrough product can be approved before clinical research is completed and to describe how and when unapproved therapies can be made available to patients while controlled scientific investigation continues. Some of these represent a formalization of past practices, but they also reflect an evolving institutional philosophy supportive of greater risk-taking in the pursuit of effective agents for patients with serious diseases.

Given that evidence of safety and effectiveness accumulate gradually during laboratory and animal testing and during the course of human trials, the challenge for FDA is to determine when public health needs are best met by saying "yes" to the availability of a promising therapy. In making this judgment, the agency must consider the caliber and the extent of available data; the potential value of a new agent to a specific patient population; the risk of toxicity; the length of time necessary to obtain more conclusive answers; and the risk that allowing broader access will impede the ability to learn more about how the therapy works. Inevitably, there is a tradeoff between speed and certainty. The sooner a drug or device is made widely available, the less that is known about it. Scientific judgments based on preliminary data are, de facto, more likely to be imprecise or wrong.

Over the past 10 years, FDA has been able to implement a variety of programs to make promising therapeutic agents more widely available to people with serious and life-threatening diseases.

Single Patient IND

As early as 1968, a mechanism for allowing investigational drugs to be given to a patient, apart from the studies necessary to prove safety and effectiveness for the NDA, was informally known as a "compassionate" use IND. Such INDs are not formal controlled trials, but they do permit use of an investigational drug under a protocol for an individual patient or patients, or for an early exploration of a novel idea. Today, the "compassionate" use concept persists and is used to describe INDs that, for the most part, involve an IND for a single, very ill patient or small group. There may be little evidence supporting the usefulness of the drug for the particular indication, but its use may be considered plausible because there is no alternative for the particular condition. Physicians may always contact FDA to propose such a use for a specific patient when they believe circumstances warrant. A similar procedure exists for experimental devices under IDEs. But when more than a small number of patients are involved, formal studies of the novel use should be undertaken.

Treatment IND

In 1987, FDA finalized regulations that allowed a "Treatment IND." This rule formalized and modified formal and informal procedures under which many thousands of patients had been given promising investigational drugs for treatment purposes, generally where there were no good alternatives. In the 1970's, cardioselective beta blockers, new anti-arrhythmia agents, and a new calcium channel blocker, nifedipine, were used extensively in otherwise untreatable patients. A formal program, called the

Group C mechanism, was established in 1976 to allow distribution by the National Cancer Institute of promising investigational cancer agents to oncologists for use in appropriately chosen patients outside of controlled trials.

The 1987 rule specifically provided access to investigational drugs for the purpose of treatment of patients with serious and life-threatening diseases for which there was no satisfactory alternative treatment. These treatment uses cannot tell us much about effectiveness, but safety data would be collected. The rule provided for agency designation of a treatment protocol after sufficient data had been collected to show that the investigational drug "may be effective," and did not have unreasonable risks. Once controlled chemical studies were well along, the FDA could permit the sponsor to recover costs of manufacture, research, development, and handling of the drug, in recognition of the fact that making the drug more widely available would represent a significant cost for the company.

Over the seven years since the Treatment IND procedures were developed, the agency has designated 30 drug or biologic investigational products for such early availability; 24 of the products have gone on to marketing approval or licensure. Of the 30 products designated, nine have been for AIDS or AIDS-related conditions, nine for cancer, and the remainder for a variety of other severely debilitating and life-threatening diseases, including severe obsessive compulsive disorder, severe Parkinson's Disease, multiple sclerosis, respiratory distress syndrome in infants, Gaucher's disease, diabetes, and others. The remainder are still under study.

Parallel Track Policy

In April 1992, the Public Health Service published a final policy statement allowing for the expanded availability of

investigational drugs through a "parallel track" mechanism. Under this procedure promising new drugs for treating AIDS and other HIV-related diseases can be made available as early as possible for patients for whom there are no alternative treatments. The parallel track mechanism -- a "track" parallel to the controlled clinical trials needed to develop the evidence for approval of the drug -- generally enables the drug sponsor to submit a protocol for earlier preapproval use of the drug than under the treatment IND mechanism. The parallel track is for patients without satisfactory alternatives who cannot participate in clinical trials because they do not meet the entry criteria, are too ill to participate, would suffer undue hardship (e.g., travel time) to participate, or cannot participate because the trials are fully enrolled. The drug is distributed to a patient's personal physician.

All drugs in a parallel track program are distributed under a study protocol so that data, particularly side effects and safety data, will be collected. Most of the data essential for market approval, however, will come from controlled clinical trials.

EFFORTS TO EXPEDITE THE REVIEW OF THERAPEUTIC PRODUCTS

Now I would like to shift our focus from wider and earlier access to investigational therapies, to mechanisms designed to increase access by expediting the review of new drugs and devices. I will describe a variety of management enhancements the agency has implemented to expedite review processes.

For drug review, we have two programs to expedite the evaluation process.

Expedited Review

To help speed the approval of new drugs that affect survival or irreversible morbidity, FDA's IND regulations formally identify a

proactive role for FDA in the drug development process. In these cases, FDA will assist sponsors in designing definitive trials at the earliest possible stage (Phase 2) to evaluate effects on survival and morbidity. Importantly, these regulations also emphasize several important safeguards for the protection of human subjects, including the requirement for informed consent, Institutional Review Board (IRB) review, pre-IND review of animal studies prior to human testing, IND safety reports and updates, review of treatment IND protocols, and adverse drug reaction reports.

If beneficial effect is demonstrated, approval is often warranted without the additional data normally accumulated in Phase 3. Additional data, for example, on dose response, long-term effects, and use in other populations, may be obtained post marketing. Examples of drug products approved during 1991 and 1992 that were designated for expedited review include didanosine, foscarnet sodium, rifabutin, zalcitabine, and atovaquone for AIDS-related diseases, and fludarabine phosphate and pentostatin for cancer.

Accelerated Approval

In December 1992, FDA published final regulations outlining a new procedure for accelerated approval of a drug or biological product based on its effect on a surrogate endpoint that is reasonably likely to predict effectiveness of the product. A surrogate endpoint is a laboratory effect or other measurement that does not itself confer clinical benefit, although it is expected that an effect on it will correspond to such a benefit. For example, lowering blood pressure or cholesterol in patients with cardiovascular disease are not beneficial *per se*, but are thought or known to correspond to decreased rates of stroke or heart attack.

The procedure applies to products used in the treatment of serious or life-threatening illnesses that provide meaningful therapeutic benefits not available through existing treatment. Where approval is based on a surrogate endpoint, the sponsor is required to conduct adequate and well-controlled studies necessary to verify and describe the drug's clinical benefit. Usually, the required postmarketing studies will be underway at the time of approval. The procedures also allow for a streamlined withdrawal process if the postmarketing studies do not verify the drug's clinical benefit, if there is new evidence that the drug product is not shown to be safe and effective, or if other circumstances arise that FDA believes necessitate expeditious withdrawal of the drug or biologic.

These efforts have allowed drugs for serious and life-threatening diseases to move much more rapidly through the development process and, in some cases, have resulted in product approval. As more products move through the system, the impact of these changes on expediting drug development should be more visible.

Several programs to expedite review also have been implemented for devices.

Fast Track

A "fast track" review system for life-saving devices and for those that offer decidedly greater clinical benefits or lower risk than existing devices has been established. The purpose is to ensure that medical devices representing major advancements in medical care reach the market without delay.

Three Tiered Review

This is a new risk-based approach to premarket review. Under the new three-tiered review system adopted by FDA, the most complex

devices and those with the highest degree of inherent risk are subject to an intensive scientific and labeling review. Intermediate risk devices receive an intermediate level of review. The lowest risk devices will receive the least extensive review.

Tier One Exemption

We are proposing to exempt the lowest risk devices from the premarket notification process, which will result in an estimated 20 percent fewer applications.

MANAGEMENT IMPROVEMENTS TO PRODUCT REVIEW

In recent years, the agency has focused on improving product review processes. The improvements cover everything from efforts to increase understanding of the application process among potential sponsors to better coordination among the different agency reviewers responsible for an application.

The Center for Drug Evaluation and Research has:

- introduced team-based project management into the review process in all new drug review divisions;

- replaced sequential review with concurrent primary and secondary review;

- developed a systemized Refusal to File policy. This policy specifies the minimum criteria for accepting an application. If these criteria are not met, the application is not accepted for review; and

- published a manual for computerized application.

The Center for Devices and Radiological Health (CDRH) has:

- Provided counsel to device companies on the regulatory "rules of the road." CDRH serves as a clearinghouse for over 1,000 publications that offer information on a wide range of topics, including development of premarket applications and compliance with Good Manufacturing Practice (GMP) requirements.

- Disseminated new guidance on application development to help industry understand what constitutes quality clinical studies in terms of statistical design, methodology, etc.

- Established a Refusal-to-File policy for device applications.

SUPPORT FOR INNOVATION AND RESEARCH

The FDA also is actively engaged in supporting and encouraging innovation and research. In addition to the product specific efforts identified above, the agency is working to help expand product development by the private sector.

Orphan Products Program

The Orphan Drug Act (ODA) of 1983 and its amendments authorize the agency to provide incentives for the development of drugs and devices to prevent and treat rare diseases. These are principally financial incentives, intended to make products that are commercially marginal more attractive to developers. These financial incentives include clinical research tax credits, grants for clinical research, and exclusive marketing rights once these products have been approved for marketing.

FDA's Office of Orphan Products Development works with manufacturers or individual researchers on the development of their products. Activities include administering the orphan designation process, awarding grants to support clinical trials of products to treat rare diseases or conditions, and providing other services in support of products to treat rare diseases. Our Orphan Products Grants Program enables FDA to provide direct support for research both on unmarketed products and on orphan uses of marketed products.

The Orphan Drug Act has been very successful in increasing the number of marketed drugs to treat rare diseases. In the decade prior to the passage of this legislation, fewer than ten products were approved for rare diseases; in the eleven years since passage, more than 100 have been approved.

It is possible for interested scientists with limited resources to develop drugs. The treatment of kidney stone disease illustrates this. Aside from drugs developed many years ago, all drugs for stone disease developed since 1980 reflect the efforts of a few interested investigators. Sodium cellulose phosphate (Calcibind) marketed in 1982 for treatment of recurrent calcium-containing stones and tioprinin (Thiola), marketed in 1988 for treatment of cystine stones in patients with cystinuria, were both developed by Dr. Charles Pak, first at NIH, then at the University of Texas. He used NIH internal resources, and other scientific grants, including an orphan product grant, found a small drug company to market the products, and brought the two drugs to market. We do not know the total cost of these efforts, of course, but it does not resemble the multi-million dollar figures attached to drug development by large commercial sponsors. Similarly, another individual physician drove the development of acetohydroxamic acid (Lithostat) for infected uric acid stones, marketed in 1983 by the same small company that marketed the other two drugs.

There are also many examples of small firms, with limited budgets, bringing important, life-saving products to market. For example, Enzon, a small New Jersey company, has two marketed drugs. The first, PEG-ADA (Adagen) is used to treat severe combined immune deficiency syndrome (SCIDS), a condition which affects fewer than 20 people per year in the United States. This product was developed in part with an orphan products grant. More recently, Enzon has received marketing approval for PEG-asparaginase to treat acute lymphocytic leukemia.

Collaboration with Office of Alternative Medicine

We commend you, Senator Harkin, for your leadership in establishing the Office of Alternative Medicine (OAM) at the National Institutes of Health. The stated purpose of the Office of Alternative Medicine is "to encourage the investigation of alternative medical practices, with the ultimate goal of integrating validated alternative medical practices with current conventional medical procedures." The resources of the OAM are also available to address some of the currently unmet gaps in access to treatments.

Over the three years since the inception of the OAM, FDA has been working closely with its staff to facilitate the OAM's efforts to evaluate those alternative practices which involve or use products under FDA's purview. Interagency meetings are held frequently, and small working groups are formed as various issues, projects, and needs arise.

Over the past year, several high priority projects identified by the OAM and its ad hoc advisory panel have been initiated with the assistance of FDA staff. These projects include the initiation of clinical trials with shark's cartilage and antineoplastons, as well as assistance in the NIH's development

of research approaches and protocols involving Dr. Revici's treatment and Bee Pollen products.

In April of this year, the FDA co-sponsored a two-day workshop on acupuncture needles with the OAM, and actively participated in the discussion on how information on the acupuncture needles could be submitted to the agency where they are regulated by CDRH. A Citizen's petition is being prepared by the acupuncture community in conjunction with the needle manufacturers for submission to the agency.

More recently, FDA actively participated in a planning meeting for a future workshop which will discuss the role of botanical products in U.S. health care. This workshop is slated to take place in mid-December, 1994.

FDA CONCERNS ABOUT S. 2140

In assessing the impact S. 2140 would have on the agency and, more importantly, on the consumer, we must begin with an understanding that the consumer protection afforded by the Federal Food, Drug and Cosmetic Act is grounded in the ability of the agency to make science-based health and safety decisions about the medical products offered in the United States. In turn, these science-based health and safety decisions are a cornerstone of the informed consent process on which patients rely in deciding what types of medical treatment to pursue. We know from experience what happens to consumers left to fend for themselves in a health marketplace.

The agency's concerns about S. 2140 can be best examined through a comparison of its provisions with the current law.

First, as structured, this bill could needlessly expose patients to dangerous products. Unlike current law, S. 2140 does not

require a company to test a drug or device in animals before selling it to humans. There will be no teratogenicity tests, which give information about potential toxicity like that of thalidomide, so that teratogenic drugs will not be given to pregnant women; there will be no tests to determine whether the drug causes cancer in animals; there will be no acute toxicity tests, of the kind that keep many drugs out of human studies altogether; there will be no tests to determine whether the drug causes acute damage to the liver or kidneys; and there will be no assessment of chronic animal toxicity prior to chronic exposure of humans.

There is also no requirement to study drugs carefully in humans prior to widespread use in treatment. A very significant fraction of all drugs tested in humans are dropped from further development because of unacceptable toxicity. This toxicity was not apparent but was discovered during the testing.

Although S. 2140 seems to contemplate allowing the use of only those products that show no evidence of harm, such a requirement can be uninformative in the absence of a requirement for scientifically valid testing. The ability to market products without clinical testing could be a very significant obstacle to broad- based systematic collection of the sort of reliable data necessary to make a useful safety determination. Under this legislation, there will be no mechanism to require the tests and no independent arbiter to review them, so people could be exposed to untested, potentially toxic products.

The kind of haphazard reporting suggested under S. 2140 is no substitute for systematic collection of data. There is no standard central collection instrument, no specific reporting requirements, no measure of exposure, and no organized assessment of reports. There is also no penalty for health care

practitioners if they do not report harm associated with treatments, and no method for any entity to enforce the requirement.

The lack of testing and independent review make the kind of protection that S. 2140 includes of little value. Section 3(b) of the bill states that a health care practitioner may provide a treatment to a patient if there is no evidence that the treatment is a danger to the person. The health care practitioner is also supposed to warn the patient of reasonably foreseeable side effects, and the patient is supposed to give his or her informed consent to the treatment.

These provisions will not adequately protect patients. The health care practitioner will not know of the actual or potential dangers or side effects, because there will be no systematic studies to find out the answers to those questions. It is extremely difficult for any individual health care practitioner, seeing a small number of patients, to determine whether a particular side effect is the result of the treatment, or is caused by the underlying disease. That problem will be exacerbated here because not all health care practitioners are trained to recognize and diagnose a wide range of adverse reactions and there will be no formal study protocol to guide them. Sometimes, as with dinitrophenol and L-tryptophan, the adverse reactions showed up months after the last dose of the drug had been taken. Moreover, there will be no overall collection of experience. Under present law, FDA looks at the safety data developed both through animal and human scientific trials and adverse reaction data collected after medical treatments are on the market, considers related drugs and approves comprehensive labeling that informs users. Such information was not developed before the Food, Drug, and Cosmetic Act and is unlikely to be developed for therapies under S. 2140.

The patient's "consent" will thus be wholly uninformed, not informed. Under current law, a patient is not considered to have given informed consent unless the patient has been advised, in writing, among other things, of the reasonably foreseeable risks and discomforts to the patient; a description of the potential benefits that might be expected, either to that patient or to others; a disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the patient; and an explanation of who will pay for the patient's care if the patient is harmed by the experimental treatment.

Here, a patient will have little to base a decision on, because no preliminary work on possible risks and benefits will have been required. In addition, the patient will not have to be told of alternative therapies that might benefit the patient, and, if the patient is harmed by the unproven, experimental therapy, there is no opportunity for the patient to be cared for by the company that sells the product. As I mentioned earlier, 80 percent of the drugs tested through careful scientific methods never make it past the early safety and effectiveness studies in Phase 2. The medical treatments offered through this bill may have the same track record. Therefore, under this bill, 80 percent of the medical treatments either will not work, or will be harmful. In either event, the patient will have to pay the bill because these experimental treatments will not be reimbursable by private insurance or government programs.

Another point needs to be considered. Since there would be no requirement for the health care practitioner to provide the information to the patient in writing, there will be no way for anyone to ascertain whether the practitioner did provide the patient with adequate information.

We are also concerned about the provision of the legislation requiring that patients be informed of the results of past applications, by the health care practitioners and others, of the treatment they will be receiving. Such information may not be based on systematic effectiveness data. Without controlled clinical trials, even if the health practitioners tried to monitor and assess the possible effectiveness of the treatment, there is no way they could do so reliably. Their observations will be unsystematic and there will no control group.

As we discussed earlier, we are working with the Office of Alternative Medicine at NIH. Although many of the alternative medical approaches have been in wide use, little if any information may be known about their safety or effectiveness for a particular patient population or disease state. It is already difficult to conduct the clinical trials to assess scientifically the safety and effectiveness of alternative approaches because of their current wide usage, and it may become even more difficult, if not impossible, to evaluate these approaches scientifically due to the reluctance of the public and the health practitioners to participate in such evaluations.

For these reasons, we are concerned that the proposed legislation, S. 2140, will undermine the efforts of the OAM to assess the safety and effectiveness of alternative approaches to medical care and treatment and to integrate them into mainstream medicine. For many of the alternative approaches, the "dangers" described in S. 2140, are not well characterized at present. The evaluations underway which are supported by the OAM will be a means to provide such information for the practicing health practitioner.

We are concerned that the broad access to unproven therapies permitted by this bill will significantly slow down conventional

drug and device development as well. We have seen situations where even the existence of treatment IND equivalents have severely slowed down the enrollment of patients in clinical trials. When scientifically sound trials cannot go forward, we all suffer in the long run, because without scientific trials we cannot determine whether a treatment works or not. As one FDA scientist put it, "the plural of anecdote is not data."

In the complete absence of scientific standards, we believe there will be nothing to prevent patients from being subjected to old-fashioned quackery. Even with the extensive and explicit requirements of the Food, Drug, and Cosmetic Act for premarket approval of drugs and devices, health fraud is a significant problem to which the agency devotes substantial resources.

In 1992, FDA took action against Conrad E. LeBeau and Vital Health Products for distributing 35% hydrogen peroxide and four other products offered for AIDS, cancer, ulcers, Downs Syndrome, emphysema and detoxification of the lymph system. Hydrogen peroxide at 35 percent concentration can cause severe intestinal burns when ingested. An injunction against Mr. LeBeau and his firm prohibiting further distribution was granted by a U.S. District Court.

After receiving a warning letter from FDA in 1994, Higher Education Library Publications ceased marketing and distribution of a colloidal silver product recommended for, among other things, cancer, septicemia, all infectious diseases, AIDS and diabetes. Colloidal silver is ineffective for all these uses.

This year FDA investigators removed several thousand vials of an imported drug product, Jin Bu Huan Anodyne Tables, from consumer channels throughout the country. The products was offered as a sedative/analgesic and was found to have caused hepatotoxicity in

at least five adults. FDA analysis revealed the presence of an undeclared active ingredient, tetrahydropalmatine, a plant alkaloid, in the product.

In the area of devices, ozone generators purported to cure AIDS and cancer were used in a Florida clinic. Four persons associated with the clinic have been indicted by a Grand Jury on 10 felony counts. One individual has been convicted and jailed. Another is in jail waiting trial. The other two have taken flights. Also, an air purifier that was being promoted for prevention of Legionnaire's Disease, hypersensitivity pneumonia, and Pontiac Fever led to Warning Letter in 1992. Other devices, the RF radiation Centi-Cure devices for improving memory and preventing/curing arthritis, high blood pressure, etc. were seized in 1991.

Eliminating the deterrent effect of the Federal Food, Drug & Cosmetic Act could give the charlatans and opportunists the green light to prey on the sick, and often frightened consumer hoping for a magic cure. This bill assumes that a health care practitioner would never make a misguided step and suggest that his or her patient use a foolish, quack product. But, unfortunately, that is not the case. Doctors and other health care practitioners have believed that medical treatments worked, only to find out that scientific studies did not support the claims.

Whether dispensers of laetrile believed in the therapy or not (in the complete absence of any credible evidence), they administered the treatment to hundreds of thousands of patients. They did not, moreover, confine themselves to people beyond hope. Many people with curable tumors were given laetrile and died because of it. This also happened with "Jim's Juice," also known as

"Cancell," a product recommended for use in treating cancer and other diseases. This was an illegal new drug made in someone's kitchen. A court enjoined its use, but not before a young child with curable cancer died after his parents quit giving the child effective therapy and gave him the totally ineffective "Cancell." Several letters in the recent issue of Consumer Reports cite similar cases of patients with lymphoma being offered chiropractic treatment and other alternative treatments, approaches never studied as treatment for a curable cancer.

We are also concerned that the only remedy the Secretary has in this bill, even when she does learn of a toxic therapy, is to publicize the fact. Now, when a medical treatment is determined to be unreasonably dangerous, we can remove the treatment from the market. This legislation would deprive FDA of any authority to remove products from the market even after there were reports of harm from responsible medical practitioners. Rather, the federal government will have to expend significant resources to engage in an ongoing educational campaign, unlikely to be fully successful, about the dangers of the treatment so that health care practitioners and their patients will not make the same harmful mistake over and over again. This brings us full circle back to the era before the 1938 Food, Drug and Cosmetic Act, when all FDA could do was warn, and had little ability to compel submission of reliable information.

We are very concerned about the broad scope of the bill. This legislation is not limited to diseases for which there is no cure or to vitamins, minerals and familiar herbs, materials with which we at least have some experience. It applies to any substance, including conventional drugs, e.g., a drug rejected by FDA as too toxic or ineffective.

Finally, we also have concerns that the bill's limitation on advertising and labeling claims would not sufficiently deter the companies who stand to gain financially out of the business of touting their products. Time and time again FDA has found that seemingly independent seminars, conventions, and press conferences have, in fact, been sponsored by the companies whose medical products were discussed at the meetings. Many journals can look reputable, but a closer examination reveals that they are nothing more than vanity presses set up by the companies whose products are extolled and advertised in their pages. In addition, these seminars and conventions will be used to attract new patients--so a health care practitioner will have an economic incentive to promote the remedy he or she offers patients.

CONCLUSION

Although our concerns are significant, we would like to work with the Committee, particularly on exploring ways to expand access to treatment when the risk of the patient's disease would warrant exposure to the potential risks of unproven foods, drugs and devices. In working with you it would be helpful to understand: what do the sponsors seek to accomplish by the legislation? What products or treatments are consumers precluded from obtaining today, and when would free access to such products justify undermining the consumer protection afforded by the Federal Food, Drug and Cosmetic Act?

Physicians and consumers already have access to a wide array of products, such as vitamins and herbs, and are free to use those substances as they see fit. Manufacturers are precluded from making claims about such products and are required to otherwise label their products accurately.

FDA shares with the sponsors of this legislation the goals of providing consumers with real choices and increasing the availability of treatments, both conventional and alternative, to the public. As described above, the agency has pursued initiatives designed to provide consumers access to a variety of effective treatments. Where serious diseases without effective therapy are involved, we have sought to make treatments available as early as possible. These methods have worked for therapies without major commercial interest, with small sponsoring companies and even interested individuals, as well as for a wide range of substances, including plant-derived substances (Taxol), natural body substitutes (carnitine, PEG-ADA, ceredase) and conventional drugs.

There is nothing about alternative treatments that keeps them from being properly studied. We are fully prepared to help design studies and assist people unfamiliar with the process.

Through the efforts of our own Office of Orphan Drug Development, and working with our colleagues at the NIH's Office of Alternative Medicine, we have moved beyond involvement in the product review process to encourage and support the research and drug development communities in undertaking development of possibly beneficial products. We certainly want to work with the sponsors of S. 2140 to find ways to enhance and improve these efforts. We would welcome the opportunity to discuss legislative alternatives that retain the current consumer protection framework and address the access issues raised by the legislation.

Thank you.

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PREPARED STATEMENT OF MICHAELA MURPHY ODONE

MY NAME IS MICHAELA MURPHY ODONE. I AM DEEPLY HONORED TO HAVE BEEN INVITED TO TESTIFY BEFORE THIS AUGUST COMMITTEE. I AM EVEN MORE, EVERMORE, HONORED TO BE THE MOTHER OF LORENZO MICHAEL MURPHY ODONE. I AM HUMBLED TO BE HERE IN HIS NAME, ON HIS BEHALF AND ON THAT OF HIS SMALL AND FRAGILE FRIENDS WITH ALD ON THE VERY DAY THAT THE UNITED STATES SENATE CONTEMPLATES BROADENING ACCESS TO MEDICAL TREATMENTS FOR DEGENERATIVE DISEASES.

CHILDHOOD CEREBRAL ADRENOLEUKODYSTROPHY IS THE STEAMROLLER OF DEGENERATIVE DISEASES. IT MAIMS, IT MUTES, IT FLATTENS PREVIOUSLY HEALTHY LITTLE BOYS ALONG ITS SINISTER PATH WITHIN MONTHS OF SYMPTOM ONSET. AND, UNTIL THE DEVELOPMENT OF LORENZO'S OIL, NO STUMBLING BLOCK EXISTED, NO HOPE AT ALL, OF HEADING OFF THOSE SYMPTOMS BEFORE THEY RACED ON, RELENTLESSLY, TO DEATH.

SOME OF YOU MAY KNOW THE STORY OF LORENZO'S OIL. ODDLY ENOUGH, IT IS NOT A STORY ABOUT AN ALTERNATIVE THERAPY. IT IS RATHER THE STORY OF A THERAPY FOR WHICH, IN 1984, THERE WAS NO ALTERNATIVE.

AND IT IS CLEARLY THE STORY OF A DESPERATE, METHODICAL RACE TO FIND AND ALTERNATIVE TO DEATH. DEATH WITHIN TWO YEARS. THE MAXIMUM LIFE SPAN METED OUT AT THE TIME BY THE OFFICIAL BODY OF MEDICAL KNOWLEDGE ABOUT ALD.

THERE IS A SAYING THAT NOTHING FOCUSES THE MIND LIKE THE KNOWLEDGE THAT YOU WILL BE HUNG AT DAWN. MY HUSBAND AUGUSTO AND I BEG TO DIFFER: THERE IS NOTHING THAT FOCUSES YOUR MIND, GALVANIZES YOUR ENERGY AND GREASES YOUR ROLLERSKATES, QUITE LIKE THE KNOWLEDGE THAT YOUR CHILD IS SENTENCED TO DIE AT SOME GROTESQUELY PREMATURE DAWN.

WHAT WE DID TO INVENT LORENZO'S OIL IS DESCRIBED IN THE JANUARY 5TH, 1989 ISSUE OF THE JOURNAL OF PEDIATRIC NEUROSCIENCES, WHICH I HAVE RESPECTFULLY SUBMITTED FOR INCLUSION IN THE CONGRESSIONAL RECORD. IT IS LESS TECHNICALLY, AND VERY KINDLY DESCRIBED IN THE WORDS OF NEW JERSEY HIGH SCHOOL SCIENCE TEACHER ILENE FRANKLIN, COMMENTING ON THE FILM, "IT WAS A THRILL TO SEE HOW THE ODONES APPLIED THE SCIENTIFIC METHOD IN THEIR... SEARCH TO FIND A TREATMENT FOR ALD. NOT ONLY WAS THE IMPORTANCE OF THE

SCIENTIFIC METHOD DEMONSTRATED, BUT THE POINT WAS MADE THAT PROFESSIONAL SCIENTISTS AND PHYSICIANS HOLD NO MONOPOLY ON [ITS] IMPLEMENTATION. IT IS THERE FOR ALL OF US TO EMPLOY."

I AM GRATEFUL THAT MRS. FRANKLIN'S STUDENTS ARE LEARNING AT A TENDER AND UNTHREATENED AGE WHAT ALL OF US HERE PRESENT HAVE LEARNED THE HARD WAY: AS SCIENCE SHEDS LIGHT, SO TOO MUST ITS PRACTITIONERS BE OPEN TO RECEIVING LIGHT!

WHAT WE NOW KNOW ABOUT LORENZO'S OIL, AFTER 7 YEARS OF USING IT ON OUR OWN CHILD, AND STUDYING THE DATA COMING FROM ITS USE IN WORLD-WIDE MULTI-CENTER TRIALS, IS THIS:

* THAT IT EFFECTIVELY ELIMINATES THE TOXIC ACCUMULATION OF VERY LONG CHAIN SATURATED FATTY ACIDS WHICH ARE THE BIOCHEMICAL HALLMARK, THE "OFFENDING METABOLITE" OF ALD;

* THAT BY ELIMINATING THESE TOXIC SUBSTANCES FROM THE BODIES OF LITTLE BOYS WHO HAVE INHERITED THE ALD GENE BUT ARE NOT OLD ENOUGH FOR ITS SYMPTOMS TO APPEAR, LORENZO'S OIL KEEPS THESE CHILDREN SYMPTOM-FREE, THAT IS TO SAY, <u>WELL</u>.

WHICH IS TO SAY THANK YOU, GOD, FOR KEEPING THESE CHILDREN SAFE UNTIL GENETIC THERAPY IS READY FOR THEM!

WHAT WE KNOW LORENZO'S OIL DOESN'T DO IS TO STOP THE PROGRESSION OF SYMPTOMS IN MOST BOYS WHO, LIKE OUR LORENZO, BEGAN TO TAKE THE OIL WHEN THEY WERE ALREADY QUITE SYMPTOMATIC.

IN OUR LETTER TO THE NEW ENGLAND JOURNAL OF MEDICINE OF 6/30/94 (WHICH I AM ALSO RESPECTFULLY INCLUDING IN THIS TESTIMONY), WE MAKE REFERENCE TO THE INFLAMMATORY COMPONENT OF THIS DISORDER. INDEED, NOT CONTENT TO BE A METABOLIC DISORDER, ALD IS A VERITABLE TWO-HEADED MONSTER, WITH AN AUTO-IMMUNE "HEAD" KNOWN TO BE ANALOGOUS TO THAT OF MULTIPLE SCLEROSIS.

In both of these diseases, tumor necrosis factor alpha (TNF) is the major cytokine responsible for the inflammation observed in the victims' central nervous system (CNS).

TNF is mainly produced by activated astrocytes and macrophages. In turn these cells become activated as a result of rising levels of gamma interferon (GINF) following a CNS lesion. BIFN, which regulates the autoimmune system by reducing the biosynthesis

of both TNF and GINF, has been shown to be safe and effective in MS in the course of extended multi-center trials. It stands to reason that it would be beneficial in ALD as well, since the inflammatory response in this disease is similar to that in MS.

BIFN would be administered in combination with Lorenzo's Oil. By dampening the inflammatory process, BIFN may give the oil enough time to dislodge the toxic very long chain fatty acids from the brain faster, thus eliminating the primary cause of the immune response and the risk of subsequent inflammation waves. (Available evidence indicates that while Lorenzo's Oil is immediately effective in removing the excessive accumulation of very long chain fatty acids from the blood, it takes two years to remove it from the brain.)

There is a plan to test BIFN in ALD children in the context of a double blinded crossover study with placebo. We find this type of trial unethical.

Prepared Statement of Berkley Bedell

Thank you, Mr. Chairman for this opportunity to testify on this important legislation. I have been involved in its formulation and efforts to perfect it. It has been a great joy to work with you and Senator Daschle and your staffs. I want to especially acknowledge the great work and cooperation of Patti Mitchell on Senator Daschle's staff. Patti had worked long hours in formulating this bill, and making corrections when suggestions have come forward for improvement.

As you know, I left Congress because I came down with Lyme disease. My Lyme disease was cured by a milk product at a cost of about $500 after pharmaceutical treatments costing an estimated $26,000 were not effective. I also came down with prostate cancer, and again it appears that a $600 alternative treatment was successful after it appeared that my surgery and radiation at an estimated cost of $10,000 had not cured my cancer.

It breaks my heart to have to tell the Lyme disease patients who contact me because their pharmaceutical treatments are not curing them, that the cow's milk treatment that I believe cured me is not available to them because of government regulations.

Mr. Chairman, we have a serious health care problem in our country today. In the United States, it is illegal for anyone to sell a medicine without spending millions and millions of dollars to get FDA permission to do so.

This causes two problems.

- First, it guarantees that we will not get low cost medicines into the system. No one is going to spend millions and millions of dollars for permission to market a product unless they can patent it and charge enough to get their money back.
- Secondly, it gives a monopoly to the giant pharmaceutical drug firms. Most alternative treatments are non-toxic, non-patentable, low cost treatments and medicines developed by firms and individuals of limited means. They do not have the money to go through the expensive FDA approval process.

The purpose of this legislation is to make it possible for people to try these treatments while prohibiting sellers from promoting then by making claims of their effectiveness.

S-2140 for the first time allows the government to set up a regulated procedure for individuals and licensed health practitioners to access the treatment of their choice. Americans who seek more options for their health will no longer have to look for medical "bootleggers" to provide them with alternative treatment options in the underground or abroad. Practitioners will know that they can be innovative and still be protected provided they follow the rigorous requirements of the legislation

Be warned, Mr. Chairman and members of this committee. There are some powerful forces that are doing very well financially under the present system. Pharmaceutical firms and some sectors of organized medicine are seriously threatened by alternative treatments. If Lyme disease patients were to be cured by the $500 treatment I received, or if the $600 I spent to overcome my cancer were to become common, it would be great for the people, but there are some powerful interests that would lose a lot of income.

To defeat this legislation, these special interests can be expected to spend whatever is necessary , using their supporters and the press, some of whom they have convinced that all alternative treatments are "quackery".

Mr. Chairman, I am living proof that all such treatments are not "quackery".

It is pretty hard to sell a worthless product without making false claims about its merit. This legislation not only prohibits sellers of alternative medicines from making false claims of effectiveness. It prohibits them from making any claims, period.

The legislation is tightly drawn. It will not change the FDA approval process. Because of peer pressure, pharmaceutical advertising, malpractice insurance problems, and insurance policies, the vast majority of doctors will not change the way they practice medicine.

But it will break the current monopoly and make it possible for people to try some of the alternative treatments such as the one I used.

Mr. Chairman, our government was established to serve the people. To protect them from powerful special interests.

We have anti-trust laws to prevent monopolistic practices. I do not think the government intended it, but unless laws are changed, the government is a partner in maintaining a monopoly in medicine.

We let people smoke; we let them drink alcohol; we let them gamble; but we will not let someone who is incapacitated with Lyme disease be treated by a milk product. What a disaster.

I challenge this great Congress, in which I was privileged to serve to give to the people the freedom of choice they enjoy in almost every other area of our society--a freedom they would enjoy if they lived in some of the other countries of the world--the freedom to choose for themselves the type of medical treatment they desire.

I urge every member of Congress to support this important legislation.

Prepared Statement of Spencer Cox

My name is Spencer Cox, and I work as the Public Affairs Associate at the Community Research Initiative on AIDS (CRIA) in New York City. I am also a member of the Treatment Action Group (TAG), and a person living with HIV

I'd like to start, Mr Chairman, by thanking you for the opportunity to address this committee I'd also like to thank you for your dedication to people living with HIV disease, and for your efforts to speed the development and availability of life-saving treatments.

CRIA is a non-profit, community-based AIDS treatment research program that grew out of the People With AIDS empowerment movement. We believe fundamentally that, until people with AIDS are integrated into every decision-making process that affects our lives and health, that those decision-making processes are unethical CRIA is predicated on the notion that real empowerment

for People with AIDS/HIV is only meaningful if there is reliable information about the safety and utility of AIDS treatments

As a person with HIV disease, I do not have the arrogance of believing that I am able to make meaningful treatment decisions alone. PWA/HIVs require the assistance of our physicians and other health-care providers, of research scientists, pharmaceutical company sponsors -- personally, I'm willing to take all of the help I can get in deciding what treatments to take

It's important that our system have the flexibility to get experimental drugs to patients who are in desperate circumstances For example, in 1988, a drug called "Fluconazole" became available in Europe and Japan for the treatment of life-threatening fungal infections that commonly afflict people with HIV/AIDS However, in the US, testing continued, and patients were unable to access this important treatment. In 1989, the People With AIDS Health Group, a non-profit "buyer's club" in New York City, began to import Fluconazole under FDA's Individual Use provisions. In ten months time, the Health Group assisted PWAs to import some $150,000 worth of the drug. In 1990, FDA finally approved the drug for sale in the US Patients who had been able to afford to import the drug had received treatment a full year earlier than most US patients. We do not know how many people died unnecessarily of fungal infections between 1988 and 1990

Programs to ensure that people have access to potentially life-saving experimental treatments have always been and continue to be central to the AIDS activist agenda We have worked with the FDA and the pharmaceutical industry to develop regulatory initiatives such as the Treatment IND, the Parallel Track, the Individual Use Allowance, and the Accelerated Approval Regulations to speed drugs to people. While we continue to work to build the broadest and most responsive patient access programs possible, these programs have made substantial progress in ensuring that experimental drugs are made available rapidly to those who most urgently need them. Consequently, for people with serious or life-threatening illnesses, the kind of radical change envisioned by this bill is probably unnecessary

It's important to ensure that we protect the safety of people with HIV/AIDS, and that we collect reliable information on the efficacy of medical treatments I'm very concerned about the safety provisions of this bill This bill would make two key alterations in the way that we regulate safety

First, it would assume that drugs and medical devices are safe until proven otherwise. This assumption is, sadly, unjustified by our experience with drug development

Second, it shifts the burden for proving that a drug or medical device is safe from the manufacturer to the FDA. This is now done for food, but not for drugs or medical devices

There seems to be an unspoken idea that providers would be able to tell if a treatment was harming, rather than helping patients. This would be true if the therapy were causing gross harm, such as the recent experimental hepatitis B treatment FIAU, which caused liver failure in most of the patients who were treated with the drug. However, it is not necessarily true of treatments that cause more infrequent, less drastic or long-term toxicities. In chronic, degenerative diseases, such side effects are very difficult to distinguish from actual disease processes, and their detection usually requires a randomized, controlled clinical trial.

I'm also concerned that the informed consent provisions of the bill allow the sponsor too much latitude in determining what baseline information must be developed on new treatments to inform the practice of health-care providers Simply telling patients that a drug is available, and that no one knows whether or not it is safe and effective could actually reduce the quality of their care by pursuading them to forego truly effective AIDS treatments Furthermore, such warnings provide little that is useful in making difficult treatment decisions

For example, after recent data raised questions about earlier studies showing benefit to treatment with AZT early in the course of HIV disease, the Public Health Service produced recommendations that patients and their physicians "consider treatment" before the onset of full-blown AIDS I see two physicians, each of whom has a different pattern of prescribing AZT, and each of whom

acknowledges that he is uncertain about his own method. These drugs that are available to treat HIV disease are not benign: their use is often accompanied by debilitating and even fatal side effects. A recommendation to "consider treatment" has not been terribly helpful in determining whether or not to risk early treatment.

Additionally, although the bill requires that patients be informed of "any reasonably foreseeable side effects," it contains no mechanism for ensuring that common side effects could "reasonably" be foreseen.

Frankly, I have yet to find a mechanism that is as effective as regulation of drug sales, to ensure that manufacturers develop this vital information. In AIDS, it has been more productive to allow patients with few therapeutic options to access experimental therapies while continuing to regulate the safety and efficacy data that are required to market a therapy. Consequently, I am concerned that the Access to Medical Treatment Act would have the unintentional effect of presenting practical disincentives for sponsors to evaluate the safety and efficacy of new treatments.

Large companies, with a name and reputation and stock prices to look after, would probably continue to study drug safety much as they do now. However, large-scale efficacy studies, which are required in order to determine whether or not a treatment really works, are expensive, time-consuming, and laborious. By divorcing marketing rights from the conduct of these studies, this bill could cause these companies to view efficacy testing as a fiscal luxury. Small companies doing clinical research would be at a financial disadvantage in comparison to other small companies that just skipped the testing phase altogether.

Three years ago, FDA passed the Accelerated Approval regulations, which allowed drugs that were intended for treatment of "serious or life-threatening conditions" to be approved based on evidence of safety and preliminary evidence of efficacy. The thought was, that by approving drugs earlier in the course of their development, we could speed access to patients, and could collect confirmatory evidence of efficacy after marketing approval. I believe that this is commonly done with cancer treatments. Hoffmann-LaRoche's Zalcidabine brand of ddC was the first drug approved under these regulations in 1991. A year later, without any substantially new data, Hoffmann-LaRoche returned to FDA claiming that their requirements for post-marketing studies had been completed. FDA seems to have decided otherwise, as they are continuing to hold the company responsible for producing efficacy data. In the meantime, the drug remains on the market, and the company continues to profit, while patients have little or no information about when, how or if we should be taking ddC. As one executive from a large multi-national pharmaceutical company recently told me, pharmaceutical companies have an obligation to their stock-holders not to conduct expensive studies that exceed the regulatory requirements. It is also important to ensure that information on therapeutic efficacy is collected in a timely fashion, which may not be possible without regulation of sponsor's profit.

Expanded Access programs like those that have accompanied development of ddI, ddC and d4T have been remarkably effective in distributing experimental therapies to patients who need them. All told, more than 20,000 individuals received ddI before approval through a Treatment IND. About 10,000 people received ddC, and 16,000 were treated with d4T. However these programs are expensive and risky: were a company to invest in manufacturing for a large-scale pre-approval distribution program, and then discover that their therapy was ineffective, they would suffer a significant loss. This committee might usefully explore mechanisms for rewarding companies that invest in these large pre-approval distribution programs, such as tax breaks on pre-approval manufacturing costs.

Finally, I'd like to say that, although I am troubled by some of the specific mechanisms by which this bill would achieve its goals, I remain strongly committed to the overall effort to provide patient access to experimental therapies, and I am grateful that this Committee has taken the time to consider the proposal. I would hope that my comments would not discourage the Committee from continuing to work on these issues, but would understand this as offering direction for future initiatives.

To quickly summarize:

- Rigorous evaluation of the safety and efficacy of new therapies is the best mechanism for achieving access to new therapies. Consequently, efforts to expand access should include incentives for controlled research, possibly including funding for study of "unorthodox" treatment modalities, such as acupuncture, and for unpatented treatments that may lack corporate sponsorship for research.

- Efforts to expand access to experimental therapies should retain strict regulatory control over evaluation of the safety of new therapies.

- Such efforts should also retain regulatory control of product sales until the completion of clinical validation, focusing on pre-approval expanded access programs like the Parallel Track, instead of on reductions in requirements for pre-marketing research.

- Companies should be offered incentives, such as tax deductions, to make therapies widely available before approval through expanded access programs such as Parallel Track and Treatment IND.

Thank you.

Prepared Statement of Robert J. Carolla

Consumers Union[1] recognizes that conventional medicine doesn't have all the answers. This is especially the case for cancer, AIDS or other tragic diseases, where conventional treatments may be inadequate or altogether non-existent.

Alternative treatments may offer benefits to consumers. We therefore commend Senator Harkin's leadership in the establishment of an Office of Alternative Medicine within the National Institutes of Health (NIH). The office offers important opportunities for practitioners to demonstrate the scientific validity of alternative treatments.

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[1]Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance; and to initiate and cooperate with individual and group efforts to maintain and enhance the quality of life for consumers. Consumers Union's income is solely derived from the sale of Consumer Reports, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, Consumer Reports with approximately 5 million paid circulation, regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions which affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

Earlier this year, Consumers Union published a three-part series on alternative medicine in Consumer Reports, focusing on acupuncture, homeopathy, and chiropractic. We found that studies of alternative treatments are few, and that most are poorly designed. In preparing the series, we had to sort through too little science, and too many conflicting claims, shibboleths, and hopeful hypotheses, in order to provide any guidance for consumer choice. We expressed strong concern over practitioners of alternative remedies who rely on anecdotal evidence or theories that aren't supported by competent research.

Consumers must be informed, knowledgeable and involved in their treatment choices. They must be able to exercise informed consent. In introducing S.2140, Senator Daschle has indicated that the bill represents a "best first attempt" to reconcile what may seem like "two irreconcilable interests": i.e., consumer protection from unscrupulous charlatans and consumer freedom to choose. We commend Senator Daschle for his efforts and intentions in this regard.

Consumers need protection, however, not just from charlatans, but also from undue risks. Freedom of choice is an empty concern in the absence of an adequate base of knowledge on which to exercise informed consent. For this reason, Consumers Union opposes S.2140. It neither enhances consumer safety nor provides for greater consumer information.

The "No Evidence" of Danger Standard

We believe S.2140 is not only a bypass of the Food and Drug Administration (FDA), but also, a step in the wrong direction within the law. In the March 1994 issue of Consumer Reports, for example, Consumers Union called on Congress to repeal the existing

exemption for homeopathic remedies under the Food, Drug & Cosmetic Act's (FDCA's) testing requirements for safety and efficacy.

S.2140 shifts the fundamental presumption under the FDCA and stands the FDA regulatory process on its head. Ordinarily, a treatment must first be proven safe before it is no longer considered to be dangerous. This burden of proof provides the highest degree of consumer protection. In contrast, S.2140 shifts the presumption so that a treatment only must show "no evidence" of being dangerous.

S.2140's "no evidence" standard is doubly troublesome because there are no testing requirements in the bill. S.2140 would allow a treatment to be used without any prior, extensive or scientific testing. The risks of a treatment therefore might only be found on a trial and error basis, in the actual treatment of patients. Informed consent and freedom of choice become largely meaningless in the absence of any compiled consumer-comprehensible knowledge.

S.2140's definition of "danger" allows for negative reactions that are no more serious than those experienced with "accepted treatments for the same health problems." It also allows for treatment if there is informed consent of "reasonably foreseeable side effects." In both instances, the bill assumes some level of prior knowledge about a particular treatment; however, there is nothing in the bill that requires the kind of testing and evaluation upon which to base such knowledge, let alone informed consent.

S.2140 is an open invitation to practitioners to use human patients as laboratory mice in unorthodox or eccentric experimentation. It provides no advance assurances of consumer safety. It does not provide for any careful, systematic assessment of proposed treatments.

The HHS Reporting Requirement

S.2140 does intend that knowledge of dangers gained by experience through actual treatments be shared and relied upon. However, the bill here too is flawed.

Under Section Four, a reporting requirement exists if a treatment is discovered to pose a danger. However, no explicit civil or criminal penalties exist for any failure to report a discovery. Even if a practitioner never again uses a treatment found to be dangerous to an individual patient, the failure to report even one case of a dangerous result would defeat the purpose of the section and the goal of consumer protection. Enforcement of this requirement is essential, but as a practical matter, any enforcement may be difficult. There is not even a mechanism by which HHS might attempt to keep track of practitioners prescribing alternative treatments.

Under Section Two's definition of danger, negative reactions are tolerated if they are no more serious than those for conventional treatments. An entire category of potential side-effects, which are relevant for consumers giving informed consent, therefore is left uncovered. Section Four only requires a certain threshold of dangerousness to be reported.

Once a report is made, the Department of Health and Human Services (HHS) has the responsibility "to properly disseminate the information." Upon introducing S.2140, Senator Daschle indicated the intention that if a treatment is reported to HHS as dangerous, "it cannot be utilized again." Unfortunately, the bill fails to make this prohibition explicit, nor does it clearly state its intended scope and application. Section Four does not cover all negative reactions, nor does it apparently trigger any further evaluations as information about side-effects is obtained.

The "No Claims" Exceptions

S.2140 seeks to promote consumer protection through its provision in Section 3(b)(4) that "no claims" can be made, including through advertising or labeling, with respect to the efficacy of a treatment. However, there are exceptions to this provision.

Practitioners are allowed to make statements about a treatment in person to an individual patient or prospective patient. As part of obtaining informed consent, a practitioner also is required by Section 3(b)(3)(c) to disclose "the results of past applications... by the practitioner and others." Furthermore, under Section 3(c), the prohibition against claims also explicitly does not apply to "accurate and truthful reporting...in recognized journals or at seminars, conventions, or similar meetings" so long as the only financial gain comes from the administration of the treatment to individuals.

Consumers Union supports the principle of open communication between practitioners and patients, as reflected in the first two exceptions. Concern exists, however, for instances in which there may be an excess of enthusiasm on the part of a practitioner, particularly where the practitioner is an apostle of a particular alternative school of treatment.

Informed consent requires full communication and understanding of treatment alternatives---which is not necessarily promoted by the legislation. A New England Journal of Medicine study published in 1993 indicated that 72 percent of people who use alternative treatments don't tell their regular doctors what they are doing.

If alternative treatment leads a patient to forgo conventional treatment by a regular physician, the result in some cases can be fatal. S.2140 fails to protect consumer interests through any specification that an alternative treatment should be used only as an adjunct to regular medical treatment or only after conventional remedies have been exhausted.

The greatest risk with alternative treatments is that of consumers falling victim to entrepreneurial charlatans. Section 3(c) seeks to protect against that risk. However, Consumers Union believes the exception is too broadly drafted. There is still a need to protect against overenthusiastic practitioners who may proselytize about uncertain treatments. Regardless of whether or not direct fees are involved, presentations at "seminars, conventions, or similar meetings," can be used to promote treatments to attract additional patients. The exception is an invitation to abuse. It allows for the informal marketing of treatments which bypass FDA review and approval.

Conclusion

Consumers Union opposes S.2140 because it is fundamentally flawed. It shifts the presumption that underlies existing standards of consumer protection: that a treatment must first be proven safe before it is considered not dangerous. It permits treatments without any prior testing and evaluation. It does not provide for the systematic collection of information on which to base informed consent. It does not adequately protect consumers against unknown risks.

We are sympathetic to patients who seek alternative treatments when conventional medicine lacks comforting or immediate answers; however, even with the best of intentions, S.2140 leaves consumers vulnerable to false hopes and undue harm.

Prepared Statement of Alexander G. Schauss

Mr. Chairman and Members of the Senate Labor and Human Resources Committee:

Thank you Mr. Chairman for the opportunity to testify at this hearing today.

My name is Alexander G. Schauss, PhD., Executive Director of Citizens For Health, a national non-profit consumer health advocacy organization with members in 11 countries and over 150 chapters in all 50 states. In 1985, I was appointed a Member of the WHO Study Group on Health Promotion that met in Copenhagen, Denmark, and have maintained numerous professional and scientific memberships and affiliations in public health organizations.

Besides being an association executive, I am also a research psychologist, certified eating disorders therapist, board certified counselor, and certified mental health counselor, who has also held various administrative positions for social service agencies in New Mexico, South Dakota and Washington state.

Imagine two fully loaded passenger jetliners colliding in mid-air with all passengers on both planes killed, with such collisions occurring every day of every week, 365 days a year. Now you have a sense of the number of deaths reported each year due to adverse reactions to drugs approved by the FDA. And that doesn't even take into account all of the tens of millions of hospital days caused by these FDA-approved products. Conventional medicine is not as safe or effective as we have been led to believe.

I reviewed the data for every year since 1982 compiled by the American Association of Poison Control Centers and published in the *Journal of Emergency Medicine*, I could not find one case of a death due to a commercial herbal product or an uncontaminated nutrient, and only a small number of cases associated with iron poisoning by young children or infants. These unpatentable herbal and nutritional products could save this country hundreds of millions of dollars in reduced health care costs. But these natural remedies will never get by the FDA's drug review process which some estimate costs in excess of $200 million to complete.

The great American inventor and scientist, Thomas Edison, said over one hundred years ago, "The doctor of the future will give no medicine, but will interest his patients in the care of the human frame, in diet, and in the cause and prevention of disease." I am sorry to say that in 1994 we are still a long way from that kind of health care system. Medical students still receive virtually no training in nutrition, and absolutely no exposure to non-drug therapies such as homeopathy, chiropractic, naturopathy, or acupuncture. What medical students do receive is an average of 1,887 hours of education on the use of drugs. So is it any wonder that we have in this country a conflict between "chemical doctors" and "natural doctors"? However, this conflict is detrimental to health care consumers. Patients must have access to those licensed providers who are trained in the use of safe, effective and cost-effective natural treatments.

Just take my own mother's experience several years ago. After five years of significant side-effects from taking various ineffective medications for her ulcers at the insistence of her doctors, she agreed to surgery, at a cost of over $10,000. But she also visited a naturopathic physician for a second opinion. The naturopathic physician promptly took her off the $190 a month worth of drugs she was taking and placed her on an herbal licorice root product which she brought from a local health food store for about $15 per month. Her ulcers literally disappeared within four months, much to the amazement of her internist and gastroenterologist who had never heard of this safe and effective therapy. When she asked them why, they responded, that they had never been

educated about treatments other than drug therapy for this condition in medical school training. I found that this therapy is fairly routine for ulcers in many other countries. Then why shouldn't all Americans be assured that they can have access to such alternative therapies if they are fully informed of any risks associated with choosing such treatment as is proposed in this bill?

Critics would claim that this legislation would open the door to quackery because it would allow doctors to give their patients remedies that are not FDA approved. But isn't it quackery to have my mother suffer needlessly for five years on $16,000 of worthless drugs, tests and treatments that failed to improve her condition? The definition of quackery as used by these critics is a mindless definition - "if it isn't a drug or conventional therapy, it's automatically quackery."

Germany had the same kind of critics in the 1970's that I expect will be here criticizing this bill. But in 1978, it had the wisdom to pass a law that opened up access to all kinds of medical treatments administered by licensed practitioners.

No, I think this bill is right on target. Thousands of non-FDA approved alternative treatments that are gathering dust could be used to treat conditions and save money when other prevailing conventional treatments have failed. For example, conventional treatments for chronic back problems can cost $40,000 if the patient has surgery. However, if the patient has one month of chiropractic care combined with acupuncture, the cost may be less than $500, a substantial savings. In my mother's case, the savings was close to 10,000%.

Since there is no rational regulatory mechanism for herbs, herbal products or nutrients to determine their safety and efficacy there cannot be reasonable warnings and/or contraindications to guide the consumer or health practitioner on its use. The current system puts the burden of appropriate use recommendations and/or safety considerations squarely on the shoulders of the health professional without any authoritative guidance. In other industrialized nations (e.g. Germany, France, Canada, etc.) rational regulatory systems for approving herb claims, for example, give professionals and consumers this needed guidance.

The Committee will be pleased to hear from our esteemed visitor from Germany that "quackery" has not been rampant in his country, but quite the opposite has occurred. In fact, by 1993, the German medical system had become convinced of the importance of many of these alternatives. Now all German medical students are required to pass a section on their final exams on the use of herbs in the prevention and treatment of disease. Soon dietary supplements will follow.

This bill expands the selection of medical treatments available for illness so that patients have other options when conventional methods fail. This legislation will not undermine the FDA's authority or detract from the conventional medical community or pharmaceutical industry, rather it will open up the consumer market to low-cost safe and effective alternative therapies. Consumers also benefit from the bill's requirement of full disclosure of the contents and possible side effects of treatments as well as mandates that patients are notified that the remedy has not been proven safe or efficacious according to the FDA's standards.

Let me end my testimony by reading three sentences written over 200 years ago by Benjamin Rush, M.D., one of the signers of the Declaration of Independence:

"The Constitution of this republic should make special provisions for medical freedom as well as religious freedom. To restrict the art of healing to one class of man and deny equal privileges to others will constitute the Bastille of medical science. All such laws are un-American and despotic."

The freedom to choose one's own form of health care is a fundamental right of Americans. This reason alone explains why Congress should support this important legislation.

I wish to thank the Committee for inviting me to testify before this historic hearing today.

Prepared Statement of Dr. Joan C. Priestley

The real, core problem with our present healthcare system is the fact that this system is not designed to promote true health. Rather, it is a disease care system oriented towards the exclusive use of high technology, expensive and rather dangerous therapies. These treatments are used only after diseases have developed.

Yet two thirds of all cancers are directly related to diet and environmental conditions. Clearly, diet changes, environmental improvement, and the use of dietary supplements (antioxidants, minerals, and B vitamins) could significantly reduce the incidence of new cancers. In addition, nutrients, herbs, and other naturally occurring compounds have been used to treat many major and minor illnesses successfully, with minimal cost or side effects.

Since 1986, I have used an array of natural products to treat over 700 AIDS patients. The vast majority of my clients maintain excellant health and lead productive lives. Over the last six years, my patients have demonstrated to me repeatedly that natural products and dietary supplements are extremely safe and effective therapies for a wide variety of illnesses.

But some people would consider that very success to create serious problems, for reasons;

(1) These products are economically competitive with drugs. Multinational pharmaceutical companies presently realize enormous profits on their FDA approved drugs and devices. These same companies have employed the FDA to "eliminate the competition" by staging armed raids on manufacturers and distributers of natural products. Similar raids on holistic physicians who dispense such substances instead of drugs.

Recent FDA regulatory actions against selected products also prove the bias of this agency. Avena sativa, an herb which allows people to stop smoking, was blocked by the FDA shortly before the nicotine patch was approved.

Saw palmetto extract works extremely well against prostatitis (a swollen prostate gland). This herb was removed just before Proscar, a prostate drug, was approved. Now the FDA is quietly applying pressure to remove boron, a mineral used successfully to treat osteoarthritis. Several new antiarthritis drugs are about to be approved.

(2) These products are clearly safer than drugs. According to the National Poison Control Centers as reported in the American Journal of Emergency Medicine, from 1983 to 1990, one American died from nutritional supplement usage. Contrast that with the thousands of deaths resulting from all major categories of perscription and over-the-counter pharmaceutical drugs.

The safety of amino acids (and other nutrients) is especially obvious when compared to drug safety. Over 3,500 people died over a ten year period from prescription and over-the-counter drugs. During the same period, only one died from nutrients.

In stark contrast to the conspicuous lack of toxicity of amino acids is the 1990 General Accounting Office (GAO) report that over half of the drugs approved as "safe" by the FDA between 1976 and 1985 caused such serious side effects as to require relabeling of the drug or its withdrawal from the market. These side effects were described as "common" and resulted in hospitalization, permanent disability, and even death. A member of the House of Representatives commented, "This is an important reminder that FDA approval does not guarantee that approved drugs are completely safe."

Why is there an adversarial relationship between the FDA and proponents of nutritional supplements? Why would a government agency designed to protect public health expend so much energy trying to suppress those who try to make safe, natural, and time-tested alternatives available to the public?

We think the FDA should be asking instead, can a reasonable person use these products safely? We think yes. The absence of significant adverse reports from the public over decades of use is ample evidence of their overwhelming safety. Certainly, no other over-the-counter drug can come close to their low toxicity.

There is the real problem. If the American public realized the safety of these natural therapies compared to drugs, the number of visits to traditional medical doctors, along with the number of prescription drugs used, would plummet. Then we could witness a sharp decline in the profits and prominence of our present health care providers.

(3) These products could exert an enormous economic impact on our society. Over 15% of our present gross national product is derrived from the business of disease care. If the population enjoyed significantly better health, they would require much less disease care. This change could have a large impact on our present system of business and employment.

In addition, better health will translate into a longer life span. Our economy could suffer if more people lived long enough to dip into our social security fund.

Moreover, our government has quietly pursued a policy of depopulation domestically and abroad, as evidenced by the recently declassified NSC Depopulation Policy Report signed in 1982 by Alexander Haig and Henry Kissinger. In order to effectively control population, we have to maintain low birthrates, and also a higher death rate. The widespread use of disease-preventing nutrients would directly counter this goal. However, we will emerge a stronger and more productive nation in the long run.

(4) Nutrients also have a profound effect on mood, memory, and behavior. People using selected nutrients in therapeutic doses will be more alert, more assertive, more activist, more likely to question senseless policies and to demand input into the decision-making process. The stately art of politics would definately enter a new phase.

(5) There is a fear that wider use of natural therapies would open the door to "quackery". The most vocal proponents of this view often have direct or covert ties with the pharmaceutical industry. The history of advances in medicine, more than other professions, is the history of visionary "quacks" who are now saluted as pioneering heros. Doctors who promoted sanitation, anesthesia, stethoscopes, and vaccinations were all persecuted and soundly denounced as "quacks". Better information and training is the best way to minimize true quackery.

Denying consumers access to information on products they want is not the American way to promote health. It is, in my opinion, tantamount to fraud for the FDA to obscure the full scientific record regarding the medical and health benefits of these safe and effective dietary supplements. This includes fiber and beta-carotene in reducing cancer risks, antioxidants such as ascorbate and vitamin E in reducing cardiovascular risks, and folic acid for neural-tube defects. The unnecessary billions spent on suppressing the signs and symptoms of ill health create substantial, avoidable human suffering and will lead, in the words of Dr. George Lundborg (Editor of the Journal of the American Medical Association), to an "imminent operational and financial meltdown" of America's health-care system.

CONCLUSION: WHAT DO WE WANT?

In summary, this issue is not just about vitamins. This is clearly a medical, public health, and economic issue. At stake are billions of health-care dollars, the quality of life that we enjoy, our freedom to speak the truth about the medical and health benefits of supplements, and our freedom to choose the kind of health care we want.

Yes, we need consumer protection. We very much want to have:

* Safe products,
* Pure ingredients,
* Full potency,
* Manufacturers standards of identity,
* Nutritional good manufacturing practices,
* Full disclosure labels, and
* Truthful and non-misleading claims.

LONG TERM SOLUTIONS:

The process of regulating proprietary substances (drugs) and non-proprietary substances (foods, nutrients, herbs) are fundamentally different. There is a need for different procedures and different expertise.

Congress should transfer all authority to review and regulate nutritional supplements from FDA to a new, independent agency. Due to the intractable bias within FDA, this new agency should not be under any FDA control, and should not be formed with any personnel with present or past FDA employment.

Specific advisory committees, with emphasis on consumer and practioner representation from affected communities, would be mandated to recommend policies relating to traditional cultural uses of herbs, foods, and dietary supplements.

We suggest that Congress establish specific priorities for research into health-enhancement effects of dietary supplements in the Department of Agriculture (USDA), National Academy of Sciences (NAS), National Science Foundation (NSF), and the National Institutes of Health (NIH) budgets.

When establishing new consumer-protection legislation requiring nutritional Good Manufacturing Practices (GMP's), make sure to include regular review by Congress to verify that FDA is not turning GMP's into punitive over-regulation of the dietary supplement industry.

The prophetic words by Dr. Benjamin Rush, a physician and signer of the Declaration of Independence are still true today.

> "Unless we put medical freedom into the Constitution, the time will come when medicine will organize itself into an undercover dictatorship. To restrict the art of healing to one class of men and deny equal privileges to others will constitute the Bastille of Medical Science. All such laws are un-American and despotic."

We request Congress to exercise appropriate leglislative oversight of an agency whose gross institutional bias is corrupting Congressional intent, blocking access to scientifically based consumer information, and arbitrarily removing safe and effective dietary supplement products from the US market.

This proposed legislation will go far toward reaffirming our Constitutional quarantees of "life, liberty, and the pursuit of happiness". Thank you also

for holding this hearing, and for according natural medicine the recognition and respect it deserves.

Prepared Statement of Dr. Jurgen Schurholz

My name is Jurgen Schürholz, M.D. I am an internist and physician graduate of the University of Hamburg School of Medicine.

Since 1978 I have served as the Chairman of the Federal Health Agency's (*Bundesgesundheitsamt*) Commission C for Anthroposophic Therapeutic Line and their Remedies, in Germany, which evaluates the safety and efficacy of therapies and remedies within the authority and purview of my Commission. Anthroposophic Medicine takes into consideration the physical, physiological, spirit and soul of the patient, insuring that each realm is attended to.

For the past eighteen years I have also served as the Chief of Service of the Filder Clinic, a 216-bed community hospital, near Stuttgart. At this hospital we practice a wide range of treatments based on anthroposophical medicine. Last year I retired from my position at the hospital to dedicate my time to the study of various natural remedies of clinical interest.

In Germany there is a long history and tradition associated with the use of natural therapies. In 1978, Germany took this into consideration when it passed The Medication Law of 1978 to provide a regulatory framework for legalizing alternative remedies. At the time this bill was being debated in our Congress, critics made all kinds of insupportable claims that the public would suffer harm or fail to use "effective" conventional therapies. After more than 15 years of experience, these criticisms have proven to be wrong. The Medication Law of 1978 was also important in that the government decided to acknowledge the following:

1.) Freedom in one's choice of therapy by the doctor, and the right of self determination by the patient, should be guaranteed;

2.) The existence and equal justification of various lines of therapeutics should be expressly recognized; and

3.) Health authorities are obliged to take into consideration the state of scientific knowledge of each line of therapy or different schools of medicine when advising the public and practitioners about their benefits.

In addition, it was also agreed upon that in all matters of medical treatment, it was ultimately the obligation of each physician to listen to his conscience when considering treatment for his patients. However, he must also be able to give plausible reasons for his choice of treatment to his patient by being informed of the merits and risks associated with any treatment he may elect to use. This is where the Commission's monographs on such remedies prove to be invaluable guides for the practitioner.

Through the work of three special commissions, one of which I have chaired for 16 years, Germany's Medication Law put anthroposophical medicine, which is studied by Commission C (while homeopathy and phytotherapy are studied by Commission's D and E, respectively), on an equal footing with those remedies of modern pharmacology referred to as "drugs."

One of the functions of these Commissions within their purview and authority is to evaluate the efficacy and safety of traditional and "unconventional" remedies and therapies by evaluating data from clinical trials, field studies, case histories, and a careful review of the scientific literature. Information is sought from all sources, including medical associations, specialists, and standard reference works. When this process is completed, monographs are issued by our Commissions and published in the German *Federal Gazette*, the equivalent of your *Federal Register*.

In Germany, physicians can acquire additional training in fields such as homeopathy or naturopathy. This enables patients to visit doctors who have a different perspective or understanding of health and the treatment of disease from that practiced by drug-use oriented physicians. In fact, since January, 1993, all German medical students must pass a section in their final examinations that challenges their knowledge of the use of phytomedicines, an inevitable consequence of the growing demand by the public for physicians knowledgeable in botanical medicine, and in recognition of the considerable scientific basis for its use in the prevention and treatment of disease.

It is not a secret that a segment of physicians and some medical associations and university faculty still continue to resist these efforts at creating a more pluralistic system of health care. However, as these "alternatives" are being repeatedly demonstrated to be safe, efficacious and cost-effective, day after day and year after year, one has to begin to question the motivation of those critics who wish to return to the old days, when doctors dared not practice alternative medicine and patients felt intimidated from seeking such alternatives.

The realization that numerous alternative or "unconventional" therapies can help patients has led to other developments in Germany that should be of interest to those working to expand access to alternative therapies in the United States.

A number of universities in Germany are encouraging faculty to direct their knowledge and experience into the study of alternative medicines. Additionally, an official Expert Group on "unconventional cancer therapies" has been funded by the government. These are just two of many examples of change that are occurring as a result of our government opening the door to increased access to alternative health care through Federal legislation.

It is also important to point out that 90% of German citizens today can receive reimbursement of alternative remedies through their insurance providers, a dramatic increase from 1988. This was accomplished after two laws were passed in 1989 and 1993 by our Federal government legalized these reimbursements for alternative treatments and remedies approved by our Commissions. Also, today all health insurance companies must cover a broad range of "unconventional" remedies not only because of their cost savings to the company, but also because they are beneficial to patients. A survey conducted five years ago reported that 60% of "main stream" physicians prescribe remedies which we would classify as "alternative", and 58% of consumers reported that they believed it is important to keep alternative remedies and treatments available. My opinion is that these figures are much higher today.

As a prime example of the growing acceptance of alternative health care in Germany, I was pleased to learn recently that the state in which I live, Baden-Wuertemberg, recently awarded forty million Deustchmarks (approximately US$30 million) to my community hospital to significantly increase space for patients receiving such care.

In summary, as a result of legislation passed in 1978, pluralistic medicine has become legally available to everyone living in Germany. Those who predicted in the 1970's that the public would be harmed or that they would fail to seek effective conventional treatments have been proven wrong.

I want to commend your Congress for taking steps to insure that Americans may have the same rights of access to alternative health care that Germans have experienced for many years. Although this may mean fewer Americans coming to our country to seek alternative therapies, we should remember that we are all part of the same healing community.

I want to thank this Senate Committee for inviting me to testify at this hearing.

Prepared Statement of Dr. Michael Janson

My name is Michael Janson. I am a physician in Massachusetts with offices in Cambridge and on Cape Cod. I received my B.A. in Biology from the University of Pennsylvania in 1966, my M.D. from Boston University twenty-four years ago, and then did a four-year residency in pathology. I developed an interest in nutrition, preventive medicine vitamin therapy and what is now sometimes called "alternative medicine" after graduation, and proceeded to found the Cambridge Center for Holistic Health in 1976 and more recently, the Center for Preventive Medicine, in Barnstable, on Cape Cod.

I am here today as the vice president of the American Preventive Medical Association. The APMA was founded two years ago as an advocacy organization for physicians who have been using nutritional, preventive and other innovative therapies with tens of thousands of patients for decades. APMA physicians all completed medical school, and have expanded on what we learned there, believing that there are better ways to deliver safe, effective, affordable health care. It must be clear that we seek not to discard the enormous benefits of mainstream medicine, but to enhance them. Our practices have been called "alternative," "holistic," "complementary," or "preventive," but we call it simply good medicine.

It is critical at this time of crisis in our medical care system that all avenues of care be explored. Doctors and patients need a wide range of treatment choices in addressing health care needs.

The Promise of Innovative Treatment

Prior to this practice, I was in the field of pathology. I observed the effects of unhealthy lifestyle choices leading to chronic, degenerative diseases. These are not being adequately addressed by the usual medical treatments:

- Cardiac disease is often treated with unnecessary and risky bypass surgery, when nutrition, dietary supplements, lifestyle change and chelation therapy with medication is less risky, very effective and less expensive. There has never been a good study showing that most bypass surgeries are helpful to patients.
- Hypertension is treated with drugs instead of diet, supplements, herbs, exercise and meditation.
- High cholesterol is treated with Mevacor instead of dietary change, supplements of the mineral chromium, vitamins C and E and garlic.

Although APMA is a strong advocate of mainstream medical treatments when appropriate, we are also aware of many effective and safe therapies involving diet, nutritional supplements, chelation therapy, stress management, acupuncture, herbal medicine, and other forms of care which are not generally accepted. If mainstream medicine were working so well, people wouldn't be seeking alternatives.

There is an enormous public demand for more choices in health care. One-third of all Americans are choosing to visit alternative health care practitioners and one-half take dietary supplements. They are willing to form an alliance with their doctors while they take personal responsibility for their own health. This will potentially save the government billions of dollars while enhancing the health of most Americans, with no significant risks. There is much research to support these innovative treatments. That they are not widely accepted is due more to inertia and resistance to change than to science. **Most importantly, however, too few physicians will acknowledge or offer these treatments out of fear of professional persecution or ridicule.**

Further research is greatly needed, **but if no treatment were initiated without conclusive research, there would be little medical treatment at all.** For practical and obvious reasons, **doctors treat patients who need help while we are still learning.** Research is ongoing in all fields of medicine, and with all treatments, but funding for research is scarce, especially for controversial therapies. For example, a recent FDA-approved study on chelation therapy had to be stopped when the pharmaceutical company which had been supplying the funding withdrew its support.

Suppression of Innovation

There is a real public health danger from preventing doctors from pursuing advancements in medicine, and restricting access to a variety of therapeutic options that licensed professionals would like to administer and patients would like to receive.

- A colleague of mine will not practice certain treatments that he has found effective because he was threatened by his HMO that they would report him to the Board of Registration— even after they dropped him from their roster! He was intimidated even though he had done nothing wrong.
- Another colleague works in my office one day a week doing treatment that he strongly believes has helped patients. In his home state, on other days, he will not use these treatments because he is concerned about what might happen to his license—he is intimidated by things he has heard, and wants to make sure he has at least one license that is not in jeopardy.
- In North Carolina, a Medical Freedom bill was passed by the legislature as a response to the public outcry over the threat to one doctor's right to practice appropriate innovative treatments that they wanted.
- In 1980, in a letter to a patient, the Massachusetts Board of Registration in Medicine wrote "...the above referenced complaint was closed...The committee members based their determination on the belief that there was insufficient evidence to recommend that the Board proceed against Dr. Janson...The Board does, however, continue to be concerned about the manner in which Dr. Janson practices medicine...**Complaint #___, while having been closed will remain in the Board office file for possible further reference.**" Their concern was that I had used vitamins as part of my treatment. Luckily I was not intimidated, or I would probably not be here testifying today.

The problem that brings us here today was recently summarized in a single sentence by a patient who said **"nowadays, when you get chronic disease you don't call your doctor you call your travel agent."** This is a sad commentary on some public perception of our health care system. Limiting access to health care choices, persecution of doctors who are doing no harm, restricting education and information about treatment choices, forcing doctors to abandon useful treatments because they are not widely accepted, and forcing patients to choose between drugs, surgery or travel abroad is neither humane nor consistent with American values. Yet professional licensing boards, insurance companies and federal government agencies are increasing their efforts to harass, intimidate and even revoke licenses of physicians offering these treatments. They claim to be acting in the public interest, but facts suggest otherwise.

Specious Arguments Against Alternatives

One of the arguments that I have heard against wider choice in health care is that ignorant or misguided patients who choose alternatives will be led to ineffective or dangerous treatments. They will thus "miss out" on the results that may be achieved with traditional medical care. Rarely is any evidence offered to support this concern. Moreover, in many cases, alternative treatment is simply better medicine.

1. APMA doctors do not ignore mainstream treatments, but use innovative therapies when they expect them to be safer and more effective.
2. Our physicians often use these treatments in conjunction with mainstream treatments, which is why they are sometimes called "complementary." Patients frequently seek both types of therapy, contrary to the charges of our critics.
3. Innovative doctors do not prey on the poor and uneducated—studies show that it is the more affluent and better educated that most often seek this kind of care.
4. There is an unfounded accusation that our practices are not based on scientific data. This is an unfair charge. There are estimates that 85% of mainstream medicine, as practiced, is not based on good scientific data. **This is not "bad," but it shows that medicine is an art as well as a science.**
5. The use of medication for purposes that are not on the list of FDA approved uses is common practice in mainstream medicine. Such "off-label" use is actually encouraged by the FDA because it is a significant source of new ideas for drug use. (In fact, the FDA only approves what can be advertised.) It is well known that once a drug is in use, doctors can use it as they deem best, based on their experience, understanding of physiology and pharmacology, intuition and knowledge of a patient. It is only with certain "hot issues" that doctors are persecuted for such off-label uses.

There is an important place for these treatments in health care. **Medicine is not a static science, but stifling innovation will make it one.** It will eliminate advances in medicine in a misguided effort to protect consumers from imagined dangers. Doctors should not be punished for pursuing their craft, in the absence of harm to patients, particularly when patients find that the treatments offer a better quality of life and are more affordable. Since patients are rarely the initiators of harassment, the record of suppression suggests that patient welfare is not the real motive. Currently, doctors and patients have difficulty in providing and gaining access to these treatments. **No one is advocating treatments that will do harm,** and APMA physicians who use these therapies are very concerned for their patients welfare. Our position is that **if patients and doctors understand the implications, risks, and benefits of any treatment, and the potential risks (and benefits) of avoiding mainstream treatments, then they should be free to choose to deliver and receive this care without fear of intimidation or harassment.**

Summary of the Position of APMA:

1. It would be a curious situation, indeed, to have less choice in health care in America, for both the doctors and their patients, than is found in Russia, Mexico, Germany and almost any other country.
2. Doctors need to have the freedom to discuss all forms of treatment with their patients and the patients need to be able to make informed decisions about mainstream and innovative treatments. They need to know the benefits and risks of alternatives and also the risks (and benefits) that may result from avoiding mainstream care.
3. APMA doctors have no interest in therapies that might harm their patients, nor do their patients wish to have government dictate their treatment options. We choose our treatments with the aim of reduced risk. We need to trust in the doctor-patient relationship, and pursue those who abuse this trust. There are practitioners who do harm through carelessness or lack of knowledge, but these practitioners are just as likely to come from the so-called mainstream.

4. Without the passage of S. 2140, some professionals will continue to be intimidated into avoiding innovative forms of care, and this will stifle the development of new treatments. It must be remembered that hand-washing, antisepsis and antibiotics were all "fringe" therapies at one time.

In my medical practice in Massachusetts over the past 18 years, I have seen over ten thousand patients. It is clear that many people are willing and competent to make their own choices regarding health care. They are not being duped, nor put in danger, and they know that their health is at stake. APMA doctors who care for them are well aware of the professional risk that they take because they are innovative. They choose to continue because they feel it is the best path for their patients. The APMA membership wants the Congress to further advancement and innovation in medicine through passage of the Access to Medical Treatment Act, which we strongly support.

Chemotherapy's Track Record

A recent issue of *Health Science* magazine offers some startling facts on chemotherapy. Since 1976, when chemotherapy was hailed as a breakthrough in the treatment of breast cancer, thousands of women were treated with the process. But according to the U.S. General Accounting Office, the therapy has demonstrated no measurable impact on survival during the last fourteen years.

The widespread acceptance of chemotherapy was based on clinical tests performed for a very short observation period. Even the researchers who reported the results cautioned that the effects on survival rates were not known.

A free copy of the report is available from the U.S. General Accounting Office, P.O. Box 6015, Gaithersburg, MD 20877. Ask for "Breast Cancer Patients Survival: Report to the Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives, February, 1989."

Examples of Alternative versus Mainstream Treatments

Michael Janson, M.D.

Submitted to the Senate Labor and Human Resources Committee, July 22, 1993.

Conditions — Treatment options

Heart disease

	Streptokinase	TPA	Magnesium
Costs	medium	high	extremely low
Benefits	mod-good	mod-good	good
Risks	mod-high	mod-high	very low

	Angioplasty	Bypass	Chelation
Costs	high	extremely high	low
Benefits	mod-poor	moderate	very good
Risks	moderate	high	almost none

Hypertension

	Drugs	Meditation	Diet/Supplements
Costs	moderate-high	none	low
Benefits	moderate-poor	good	excellent
Risks	moderate	none	none

Allergies/Asthma

	Drugs	Diet/supplements	Desensitize
Costs	moderate	low	mod-low
Benefits	moderate	good-excellent	excellent
Risks	mod	none	minimal

Prostate enlargement

	Drugs	Herbs/Supplements
Costs	moderate	low
Benefits	mod-poor	good
Risks	significant	almost none

Statement of ACT UP San Francisco

Dear Senator Harkin and Members of the Senate Labor and Human Resources Committee,

In the battle against AIDS, as in all struggles against life-threatening illnesses, we must pursue a course which includes all potentially viable options for treatment. People with AIDS (PWA's) and other life-threatening illnesses must be consulted, included, and empowered during the process of developing new or individualized therapies. Given the results of the Concorde Study and other research indicating that anti-retrovirals are less efficacious than previously believed (especially with regard to early intervention) alternative options such as anti-oxidants, amino acids, immune modulators, herbs, and other non-approved or experimental therapies become even more crucial.

After twelve years of tragically wasted research, money, and energy, there are no effective drug treatments for AIDS. The so-called anti-retroviral AIDS drugs (such as AZT, ddI, ddC, d4T) have failed to extend the lives of people with AIDS. Largely ineffective, yet very costly drug therapies for AIDS create a crying need to research alternative therapies and explore a more holistic paradigm with regard to treating and controlling disease progression utilizing a combination of approaches.

Access to natural, traditional and alternative treatments is an absolute right which consumers will not give up. Many of us in the west coast AIDS community must obtain the treatments we need from underground sources because pharmaceutical manufacturers and/or FDA are uncooperative in expediting access to these therapies. Some of us are forced to manufacture our own treatments because they are unpatentable and therefore less profitable for pharmaceutical manufacturers.

The issue of access for us has to do with who controls health care. The AMA/FDA/multinational pharmaceutical companies must not be the sole arbiters of medical truth, and they must not be the controllers of access to all medical treatments. The assumption that People with AIDS and other life-threatening illnesses are too stupid and desperate to make rational and informed treatment choices is an insidious and paternalistic assumption which many bureaucrats, physicians, politicians, and even a few AIDS activists, share. In the so-called "enlightened" San Francisco Bay Area, there are doctors who refuse to treat or work with PWA's unless those patients take AZT. The issue of access has not only to do with who controls and profits from medical treatments; it has to do with choice. We in the California AIDS community demand the right to make our own treatment choices.

Since many People with HIV/ AIDS are rejecting conventional anti-viral therapies as ineffective, toxic, and too expensive, legislation which protects the right of the individual to choose non-conventional or unapproved treatments becomes crucial for a number of reasons. First, a majority of PWA's would prefer to work with physicians/practitioners in making treatment choices and evaluating lab work and efficacy. This is virtually impossible when many of the therapies which individuals seek are not approved by the FDA. Patients cannot be honest with care-givers for fear of losing the services of those care-givers or jeopardizing the careers of clinicians who become complicit in ordering blood work for a patient using an underground or "illegal" therapy. As it stands now, many patients cannot seek the advice of professional care-givers with regard to a host of treatments we in the AIDS community actually use. Among these are injectable glyzheriason (licorice extract), TAT inhibitor (an underground version of Hoffman La Roche's TAT inhibitor) combined with the anti-oxidant drug Trental, the non-patentable topically applied cellular immune drug DNCB (Dinitrochlorobenzene), Hyperthermia, Bitter melon, colloidal silver and other compounds and treatment strategies. These and similar therapies are successfully lowering viral load (the level of detectable viral activity in the blood), increasing the number of "natural killer cells" (those cells which actually inhibit replication of HIV), strengthening our resistance to opportunistic infections (the infections which ultimately kill PWA's), and improving our health and well being. The legal status of any of these treatments is irrelevant. We in the AIDS community will continue to use them as long as we find them to be effective regardless of the political or legal ramifications. If it is necessary, we will also continue to lie to our doctors and government sponsored service agencies to insure access to treatments of choice. We would prefer to be honest concerning our personal therapy protocols. However, until we and our care-givers are protected, we will do *whatever* we must do to insure access to potentially effective modalities. If we have no other choices, we will continue to manufacture our own drugs to assure access and affordablity.

Legislation which promotes freedom of treatment choice and honest dialog between doctors and patients is critical at this moment in history not just to minimize and prevent potentially harmful underground therapies from reaching unsuspecting PWA's. It is important not only to foster a robust, open, and ongoing national debate and discussion concerning treatments for AIDS. Education and frank discussion are the modes and models for self-empowerment. We do not need more government regulations which insist that the "experts" (physicians and FDA/ government scientists) know so much better than people with life threatening illnesses which treatments we should choose and what we should and should not put into our bodies. The Access to Medical Treatment Act is necessary to help promote a new paradigm of medicine which includes and empowers patients. We can no longer rely entirely on the limited vision of those who would indefinitely continue to dispense AZT and chemotherapy at the expense of exploring completely new strategies for AIDS, cancer, and other chronic and life-threatening diseases. With the introduction of the new diagnostic technology (PCR or Polymerase Chain Reaction and Branched Chain DNA to measure viral load), doctors and patients can work together to evaluate individualized therapies very quickly. Once the diagnostic tools are in the hands of the people (not exclusively in the hands of the "gate-keepers" such as scientists and clinicians), data can be shared via computer networks, newsletters, and other means, to educate patients, doctors, researchers, and the general public about potentially effective treatments and combination strategies. This new paradigm could, of course, save hundreds of millions, even billions, of wasted research dollars. The savings could be invested in treatment programs that really work for a majority of patients or specific sub-groups of the population.

The Access to Medical Treatment Act has been criticized because it may promote dumping of unproven, unapproved treatments onto a vulnerable market place. Critics further point out that the flow of research and information might be partially squelched because pharmaceutical companies could promote drugs directly to doctors and patients without any proof of efficacy. This, of course, assumes that the whole AIDS, cancer, and other communities are totally naive and possess no means of oversight for spurious claims and completely unsubstantiated data. This is simply not the case; it is more likely that dialog and exchange of research data, especially on non-patentable and "orphan" drugs and compounds, would be encouraged, not hampered. With regard to the potential problem of major pharmaceutical companies taking

advantage of the law and dumping their unproven, inadequately researched products onto the market, Senators Dashle, Harkin, and Pell should consider an amendment which would successfully address the issue without jeopardizing access. ACT UP San Francisco as well as many other individuals and AIDS organizations throughout the country would be quite willing to assist in drafting amendments to this and other legislation which vitally concerns us. Many of us in the alternative treatments (for AIDS, cancer, heart disease, etc.) communities have been left out of the loop for too long.

ACT UP San Francisco joins other AIDS, Cancer, Alzheimer's, and Women's groups in supporting and urging the passage of The Access to Medical Treatment Act. This law will be a small but critical step in the direction of patient/consumer self-empowerment. People with AIDS will not be denied the right to choose treatments or access information. With or without this law or a governmental or bureaucratic seal of approval, we will do what is necessary to preserve and defend those rights.

STATEMENT OF STEPHEN K. ELSASSER

Dear Senator Harkin:

Please enter my written testimony into the hearing record of S.2140, The Access to Medical Treatment Act, held on July 22, 1994.

It is imperative that any federal, state or local medical healthcare programs provide freedom of choice for the public to seek not only the physician of their choice, but access the type of services and treatment which they so choose without prejudice or economic penalty. It seems to me that much of the debate over healthcare reform not only speaks to access but also speaks to economic caps which can restrict services. The decision makers who decide which services should be restricted are often in the "orthodox" camp and are prejudice against "alternative" medical practices. We cannot allow this type of bias to appear.

I have practiced medicine for 16 years now, both in allopathic and "alternative" medical service areas. I recognize the value of having drugs, surgery and standard therapies available to our patients, but I am also keenly aware of the many failures that this type of "crisis" care can provide. It has many limitations in that it does not speak to the underlying cause of disease. Alternative medicine, on the other hand, does seek diligently to find the cause of the illness and often times this is attainable. Through "natural" remedies, many of these chronic diseases which are not correctable by orthodox methods, are often resolved. To many patients throughout the midwest, our clinic has been a bastian of hope and often times provided significant relief, many cures, and happiness to patients who have not been able to be helped with standard medical practices. Frequently, and history can record,

most great discoveries do not occur in an ivory tower or a sophisticated research center, but in the private practice of an individual who is innovative and observes certain positive effects in the treatment of human suffering. If government allows restrictions to be placed upon individuals so that they are penalized economically or otherwise from seeking alternative practitioners, then this innovation and progress will certainly slow down, if not cease. It is therefore imperative that all citizens have the right to choose the physician and therapy of their choice without penalty. If this is followed through appropriately under your Access to Medical Treatment Act, then competition and times will select out the good therapies from the bad, the cost effective therapies from the expensive ones and we will all be better off. The American people are educated enough and have enough common sense to be able to determine what works and what does not work, which is toxic and non-toxic, and where they want to spend their money, if we will only allow them to do so.

I trust this information is helpful to you in formulating the policy which works best for all Americans. If I can be of further assistance, I will be most happy to help.

Statement of the American Association of Naturopathic Physicians

The American Association of Naturopathic Physicians (AANP) supports the Access to Medical Treatment Act (SB2140) introduced by Senator Tom Daschle and, in the House, by Congressman Peter DeFazio. The AANP represents naturopathic physicians (NDs) who are qualified through education to be licensed to practice primary care, family practice, naturopathic medicine.

Naturopathic physicians practice a form of medicine which provides effective and scientifically based natural therapies for the alleviation of disease, while emphasizing prevention, patient education, individual responsibility for health, and a healthy lifestyle. We are experts in clinical nutrition, therapeutic exercise, botanical medicine, homeopathic medicine, psychology and lifestyle counseling, and acupuncture. In many ways, we are the modern form of the family doctor of old, but with a profound belief in the inherent ability of the body to heal itself when given the opportunity and the necessary support.

The Clinton Administration has started Americans on the path towards long-needed health care reform. What has become obvious, however, is that there are many different and often conflicting ideas about what health care reform should be. It is also clear that the cost of reform is potentially very high. Regardless of what bill passes Congress this year, it is clear that the medical paradigm the nation has been laboring under for so many years is undergoing an evolution. The United States can no longer afford to spend billions of dollars on health care

in the face of rising disease rates and inadequate coverage for a growing number of Americans. It is time to address preventive medicine and wellness programs, and to make room for less costly therapeutic approaches.

Alternative medicine focuses on prevention and wellness rather than disease palliation with drugs and surgery. Alternative medicine, by placing the emphasis on nutrition, patient education and prevention as part of primary care, will ultimately lower the cost of American health care.

Alternative medical practitioners offer safe, sensible and effective health care options unavailable from conventional medicine. Such practitioners include medical doctors, osteopathic physicians, naturopathic physicians and related health care providers such as acupuncturists, chiropractors, midwives, nutritionists, physicians' assistants, nurse practitioners and massage therapists. Together, they represent a healthy cross-section of America's health care options.

Alternative medical practitioners also work well with conventional doctors. Examples can be seen in both Oregon and Washington, where osteopathic, medical and naturopathic doctors are licensed as primary care physicians. Interdisciplinary referrals and, most important, patients' freedom to choose the form of medicine they wish, have formed a medical system which ultimately lowers costs while delivering optimal health care. Studies have shown that, when alternative medical practitioners such as naturopathic physicians are utilized, health care costs diminish.

Alternative medicine must be part of any health care reform package; otherwise, we will have failed to address the core issues in long-term cost reductions, and that failure will continue to feed an already over-costly medical system and place further burdens on taxpayers and businesses.

Traditionally, Americans had access to the medical treatment of their choice. The forces which historically drove their decisions were effectiveness and outcome of treatment. The free-market system dictated which form of medicine the consumer chose. This tradition has largely been lost, and Americans no longer have many options, except in a few states where alternative medical practitioners are licensed.

Many alternative medical practices which were once part of conventional medicine have been largely replaced by drugs and surgery, which are far more expensive, have far greater side effects, and are often unnecessary or ineffective. Many alternative medical therapies such as botanical medicine, nutritional supplementation, homeopathy and physical medicine have a long history in American medical practice, and these tools remain in daily use in India, Asia and most of Europe. Their effectiveness and safety when utilized by trained practitioners are well documented.

Our current health care delivery system has become top-heavy with specialists who are taught to focus on a narrow segment of a person's health. We have strayed very far from the family doctor who often served several generations of the same family. Our current system has narrowed its therapeutic options to drugs, surgery and radiation, while ignoring the huge field of natural medicine. The present system is out of touch with the medical paradigm now emerging. The United States is one of the very few countries which does not include some form of alternative medicine as a health care option. As a result, we have more chronic degenerative disease and higher cancer rates than many other industrialized countries, even though we spend more on health care.

According to Joseph Beasly, MD, in his report to the Kellogg Foundation:

"There cannot be much doubt that modern medicine's paradigm and resulting methodology are failing us on the most critical front, the spread of chronic disabling and killer diseases. With its classical science paradigm and methods -- specific etiology -- it is shooting arrows at the storm. It neglects newer systemic findings about nutrition, behavior and human ecology.... In the struggle with degenerative disease it is hamstrung by its hyperspecialization and tunnel vision. It seems modern medicine has grown progressively narrow, ineffectual and expensive."

This is why the Access to Medical Treatment Act is needed, and why it must be a part of health care reform. It broadens the field of options and does not increase costs; indeed, it will decrease costs in the long run. This bill does not take away the rights of states to regulate the practices of medicine, nor the ability of the licensing boards to review these practices.

The Access to Medical Treatment Act does allow the public to decide the course of health care reform by maintaining medical treatments already available. This Act will let Americans decide what the medical marketplace should be. It will ensure the continuation of a long tradition in health care.

The American Association of Naturopathic Physicians urges you to take the leadership role Americans are asking Congress to take, and pass the Access to Medical Treatment Act.

Statement of Arno Nording

I am submitting this personal testimony to the Senate Labor and Human Resources Committee, in the hopes that you will support S-2140, the Access to Medical Treatment Act. This Act would guarantee access to health care practitioners with any method of medical treatment within the framework established by the Act, which provides for notification and consent procedures to ensure that the patient understands and consents to the treatment being given, and excludes any treatment reported to be dangerous.

I am very concerned, and hope that I will continue to have access to health care practitioners of my choice, including acupuncturists, herbalists, chiropractors, and any other reputable practitioner that I may need the services of in the future.

I became interested in alternative medicine, primarily Traditional Chinese Medicine, after several frustrating years of trying to treat stress-related disorders with prescription drugs. At that time, several prescriptions were tried on me, such as Mellaril and Haldol. Each time, it took at least one week of discomfort before it could be determined whether the medication was "appropriate." Once an "appropriate" medication was settled on, often additional medication was prescribed to deal with side

effects, such as muscle stiffness, caused by the primary medication. Most prescriptions also made me somewhat drowsy, and made it more difficult for me to concentrate.

At that time, I was also subjected to several tests, including an EEG, brain scan, and a glucose tolerance test. None of these tests proved to be of any diagnostic use. Finances were not a problem for me at that time, since I was eligible for the state-sponsored Medi-Cal program, but this set of tests surely must have cost the taxpayers quite a bit of money.

I decided to try Chinese herbs, in hopes for a better cure. I immediately noticed the difference in diagnostic methods, in that all of my symptoms were considered in deciding the course of treatment. My previous experience with medical practitioners is that they deal with only specific symptoms, often ignoring other symptoms which may seem irrelevant at the time. I would also like to state that, once a general herbal formula was prepared for me, only small changes were necessary in the future, in order to "fine-tune" the formula for me. Such adjustments were not possible with prescription drugs, since I was taken completely off of one drug and put on another one.

My treatment with Chinese herbs proved itself to be very effective within a couple of weeks. I continued to take the herbal formulas for two years. After that period of time, I no longer needed to take the herbal formulas on a regular basis, as I was able to stay alert all day long, without fatigue. Such a permanent improvement in my condition is something prescription medication would have never accomplished for me. Furthermore, there are no side effects from Chinese herbs. Finally, I would like to point out that the treatments would cost me $50 to $100 per month, much less than the costs of regular doctor visits, prescription drugs, and tests. Since I am no longer eligible for Medi-Cal, and do not have private health insurance, choosing a Chinese herbal practitioner was one of the wisest decisions I have ever made.

In February, 1990, I began feeling the oncoming of an ulcer. I regularly felt a strong burning sensation in my stomach when eating or drinking. I returned to my Chinese herbal practitioner, and obtained a formula. After one month of taking the formula, my ulcer was completely gone.

In May, 1991, my back became extremely sore after getting up quickly from a chair. The pain kept getting more intense every day, making it very difficult for me to move around. I visited a chiropractor. I noticed a big difference after the first visit. I continued twice a week, then once a week, for several months. The pain would come back every so often, but over time, my back condition improved enough so I did not have to return to the chiropractor any more. The cost was $25 per visit, a tiny fraction of the cost of back surgery, and without the risks of surgery.

I have recently used Chinese herbal practitioners and acupuncturists for the treatment of digestive orders, insomnia, and many minor ailments. The low cost and the lack of side effects keep me choosing Traditional Chinese Medicine. On the other hand, friends of mine that have gone to doctors and hospitals have been subject to numerous unnecessary tests and medications, making treatments for even simple ailments add up to hundreds if not thousands of dollars.

Unfortunately, recent actions by the Food and Drug Administration as well as the California Food and Drug Branch threaten the availability of Chinese herbs, as well as make it very difficult for practitioners of Traditional Chinese Medicine. FDA policy recently prohibited the dissemination of even the slightest hint of a therapeutic benefit of a particular herb or other dietary supplement on its label or accompanying literature. Access to herbs and other supplements are in jeopardy by sections of the Advance Notice of Proposed Rulemaking, issued by the FDA on June 18, 1993, which the FDA has to date still not retracted. The California Food and Drug Branch also maintains a list of safe Chinese patent medicines as being "Category III Potentially Hazardous Imported Drug Products," merely because of an indication of a therapeutic use. Only few states currently have legislation protecting physicians from losing their licence just because they recommended an alternative health care practitioner, even if the patient had much better results with that practitioner.

Bearing in mind the unnecessary suffering from undesirable side effects of prescription medications, unnecessary tests and

procedures, and the impersonal nature of many of today's medical practitioners, I ask you to keep the avenues to alternative health care practitioners open, for me, and for everyone else who may at some point choose to use one. In times where health care costs are bankrupting our country, when prescription drugs kill over 60,000 people every year, I hope you will ensure that those individuals who choose to use alternative health care practitioners will continue to have the right to do so.

This Act provides that the patient be notified of, and consents to, the nature of the treatment and whether any methods have not been approved by the FDA. Other provisions protect the patient from treatments that may prove to be dangerous. The key point is that the informed patient, the one whose life is at stake, be allowed to make the choice. I therefore hope that you will approve this legislation.

Statement of Frank A. Manson

I am most appreciative of your invitation to those attending your hearings to contribute to S. ~~2107~~ 2140. This bill looks to the future of medical care and the day when all effective therapies, both traditional and alternative will share the common goal of improving the quality of health care along with the quantity.

The current health care debate has focused on who should pay for health care and who should receive it. Too little has been said about improving the quality of health care, the assumption being that America's medicine has reached it's very pinnacle. The reality is that America's traditional therapies can do very little to prevent and treat degenerative diseases such as cancer, senility, alzheimers, arthritis, diabetes and the number one killer of them all, cardiovascular disease - - heart attack and stroke. Traditional medicine relies mainly on drugs and surgery. Alternative therapies engage more innovative and unpublicized methods. Many alternatives have proven effective.

Physicians attracted to alternative therapies are not run of the mill doctors. For example alternative doctors from coast to coast trained in traditional practice, doctors such as Maryland's Paul Beals, Pennsylvania's Conrad Maulfair, South Carolina's Theodore Rozema, Illinois' William Mauer, California's Murray

Susser are all on the cutting edge of tomorrow's medicine. I have recently talked to all these dedicated and courageous doctors. All of them treat, teach and preach total medicine, everything from herbs, vitamins and chelation to antibiotics and surgery. They are looking beyond today's medical horizons - - looking for true prevention and cure. They, along with innovative medical technology - are true pioneers of the 21st century.

The Berkley Bedell experience is typical of the increasing number of Americans now turning to alternative therapies after they have been told there is no effective treatment. In my own case I was told by the top cardiologist at Johns Hopkins University Hospital that nothing could be done to help my angina and general weakness following a massive heart attack. Yet, EDTA Chelation Therapy has helped me. I have personally benefitted by chiropractic therapy from a traditional untreatable "winged scapula". My shoulder blade had protruded three inches beyond normal position. Now it is cured. My wife's painful arthritis of the knees was cured by oriental acupuncture some years ago.

Two former California Congressmen, Bob Wilson of San Diego and Patrick J. Hillings, have had their arteries cleaned by chelation. I recently talked to Bob Wilson. He tells me his therapy has lasted him 15 years now, although he still takes maintenance about once each month. Bob's chelation doctor, William J. Saccoman M.D., now in his 70's told me he has now treated over 15,000 with EDTA chelation with zero mortality.

Yet, a recent letter from FDA was forwarded to me by Senator Orrin Hatch's office stating EDTA Chelation is dangerous unless it is used as a therapy to remove lead and heavy metals from the bloodstream. The FDA does approve its use for heavy metal removal both for children and adults. In researching a book I am just completing on chelation therapy which at Bob Wilson's suggestion I'm calling "The Lifesaver", five chelation administering doctors have told me that both former President Nixon's life and that of his wife Pat could have been extended had they received chelation. And President Nixon had ordered a book on chelation from Arline and Harold Brecher, noted authors only a short time before the President's fatal stroke. The Brechers still hold Mr. Nixon's check. They knew it had its historical value and did not cash it.

One of the doctors who said chelation would most probably have avoided strokes by President and Mrs. Nixon is cardiologist Dan C. Roehm M.D., formerly chief of Department of Medicine at Broward General Hospital, Dade County, Florida. He said he had gone through a personal experience with his wife that converted him to alternative medicine.

Dr. Roehm's wife had gone through a series of minor strokes (carotid stenoses) and it was only a question of time until she had a fatal stroke.

"Although I was a cardiologist and a surgeon I could not treat her," said Dr. Roehm. "That's when I tried her on EDTA chelation. It worked. Since then I've become a believer and introduced chelation into my practice."

After his long and dedicated life in medicine both as a traditionalist and more recently alternative therapy, Dr. Roehm summarized our situation as follows: "We in America are brilliant diagnosticians. We're the best. Yet, we cannot effectively treat the degenerative and difficult disease. Sooner or later all of us if we live long enough will require such treatment. Some one should tell such people as Ted Williams and Bobby Feller about chelation."

I was touched by the testimony of the father whose five year old daughter was suffering from neuroblastoma cancer; got help from a 98 year old Dr. Revici in New York and then was threatened by an NIH Doctor for going outside traditional medicine for help. Mr. Chairman my wife and I had a five year old daughter die from neuroblastoma. The doctors at the U.S. Naval Hospital Bethesda tried everything they knew; but they could not stop the ravages of that awful disease.

I urge the Senators of the Committee to take advantage of the Health Care debate to introduce alternative therapies to the overall health umbrella. There should be no fear from mainstream medicine that alternative therapies will push drugs and surgeons into second place. In New Zealand, for example, in heart disease chelation is sometimes recommended. If that fails, they go to surgery. The objective is to save the patient's life and to improve the total quality. I strongly support Senators Harkin and Daschle's statement that they must find a way include alternative medicine

with health care reform.

America's health objective should be both quality and quantity. "Get the bestest to the mostest." Thank you.

I enclose a copy of an editorial I am sending to a few newspapers.

Statement of Nancy A. Hilbert

Attn: Mr. Harkins:

Please enter my written testimony into the hearing record for Bill S2140 (Access to Medical Treatment Act).

Living here in the Ohio River Valley, I have been bothered with sinus infections and allergies for several years. Starting in the fall of 1990 I began having re-occurring sinus infections on the average of every four to six months. I always missed approximately two days work and had to be put on antibiotics prescribed by my family doctors.

February 1993, I came down with another sinus infection and my husband suggested I see his doctor. I went to Dr. Kirk Morgan and he made the suggestion that I use Hydrogen Peroxide Food Grade in my drinking water as a preventive treatment for my condition. Since then I have not had one sinus infection and I believe it is because of the treatment Dr. Morgan suggested. I have even told my family and friends about this and they are also trying it.

I support this type of treatment and also the doctors who use it in treating their patiences.

Statement of Carol McGrath

Thank you for the Senate hearings regarding the Access to Medical Treatment Act, S.2140, sponsored by Senator Daschel. I am very much in favor of S.2140. Please bear with me as I ask you to imagine several things. There is a point to be made.

Imagine that you are a productive, hard working individual. As that holds true for all of you, that should be an easy one to imagine. Imagine that you have recently married and you want, anticipate and work hard to save money for a home, starting a family, etc. Imagine that one day you become ill enough to require a visit to the doctor. He or she prescribes medication -- in a couple of days you're back to work. A month later, you're in the doctor's office again -- same symptoms, same medication is prescribed. You return to work. This pattern continues and one day you collapse and are rushed to the hospital. All the normal testing is done. You are told they are unable to find anything wrong -- only you still don't feel well. Because you're job is considered a high stress

job, a sedative is prescribed and you are sent home. Determined to be the productive, hard working individual you have always been, you take the medication and return to work. The medication, however, does not help and you again collapse. This time, however, you are unable to return to work. Looking for help, you go from one doctor to the other until finally, you find a practitioner who has a different protocol from the one which has proven unsuccessful for you. This protocol includes, but is not limited to, acupuncture and nutrition. Although not the magic bullet you have been hoping for, it helps and ever so slowly you begin to feel better. However, months have gone by before you were able to find the right practitioner. Your condition worsens. Not only is working impossible, but you are too ill to do anything at all. Plans of purchasing a home and starting a family are no longer a thought. Your social life disappears, and the productive, hard working individual you once were is now a frail, unproductive burden on society, family, and friends.

If you were able to bear with me thus far, please bear with me a little while longer and imagine another scenario.

Imagine that you become ill, only this time a host of health care practitioners, each licensed, each with their own specialty, are available to you. He or she determines the appropriate protocol for your circumstances, and you recover. You are able to return to work and remain the productive, hard working individual you have always been. Plans of purchasing a home and starting a family continue and your social and family life is enhanced. You do not become a burden on society, or on anyone else. You do become a healthy, happy individual with enough energy and stamina to help yourself and those around you.

Honorable Senators, the first scenario is the one I, and thousands of other Americans, have had the misfortune to experience. The second scenario is what S.2140 will accomplish -- a healthy and productive America.

Which scenario will you pick for your lives, your children's lives, your grandchildren's lives, and for the future of America?

Statement of Hilda Patti Howell

Product information and literature from books and handouts have helped me to learn how to take care of my body. The availability of this material is essential and should never be taken away from us, it is a freedom granted us by our Founding Fathers.

Re: My health and Natural Methods over Allopathic.

1987 July 16 Nuclear Ventriculogram for heart test. Stannous pyrophosphate and sodium pertechnetate Tc -99m 35mCi. Allergic reaction several hours later queer feeling followed by weakness, unable to stand. Chills - constant body shaking for 30 min. Fighting to stay alert, drank approx. 1/2 gal water to dilute and flush from body. Put SunBreeze [Sunrider product] on my tongue which I had in my purse and it flashed into my mind. Immediately body stopped shaking and a calming flowed over my body. Exhausted, weak unable to walk by myself for hour to two hours.

After heart racing, skipping beats and several trips to the hospital emergency room where nothing showed up, it dawned on me that by putting the SunBreeze on my tongue this might have stopped the reaction. So one morning as I got out of the shower I had a spell with my heart. I called my doctor and told them I was coming right in and wanted an EKG as soon as I arrived. By the time I got there I was weak and they brought a wheel chair,

and took the EKG as I sat in the wheel chair. The doctor took one glance at the chart and turned around and said, I'm calling an ambulance. I ask my husband for my purse and put SunBreeze on my tongue. When the ambulance arrived I felt much better, at the hospital they could find nothing again. But the EKG from the doctors office showed them I did have a problem, it was not just in my head. Back to. . . .

1988 April weight 83 lbs, down from 96 lbs. Every day harder to keep going, couldn't find out what was wrong. Our daughter an RN suggested I get a blood test for Hepatitis. Doctor instead of a blood test ordered a liver scan.

1988 May 9 Injection of 5 mCi of Technetium Sulfur Colleid, liver was scanned in multiple projections. Appears normal, no enlargement or filling defects. Spleen is normal.

Several hours later - allergic reaction. As I approached my car with an arm load of groceries, cars going by on the street appeared as on gently ocean waves. Afraid I could not make it back into the store and explain my situation and not having to cross any traffic getting home, I drove home, called the doctor who told me not to drive but get a neighbor to bring me to his office. By then I was thick tongued, feeling strange. A neighbor just drove in as I was talking to the doctor, she took me and I was given a cortisone shot.

Still searching for help I recalled a man telling about going to Germany where he found by using a Dermatron machine they diagnosed where his problem was and what to do for it. He said he brought back word of this machine and there were a few in the U.S. then. **Calling around the country I located one at the Century Clinic in Reno Nevada.**

Century Clinic said I could get an appointment in December. I told them I didn't think I would be around that long the rate I was going. She found a cancellation the next week, I took it.

1986 May 7 I visited Century Clinic.

My insurance records show Loss of weight, Fatigue, Mental dullness, Chronis Viral Infaction, Liver dysfunction, Multiple allergies, Candida Albican.

Checking different organs in my system by using the accupressure points on my hands the dermatron machine showed my liver was absolutely loaded. Hepatitis, herpes virus like shingles, salmonella they could even pick up what childhood diseases I had when a child. They mixed up an injection and gave me. In the morning when I looked in the mirror my eyes just sparkled, I kept going back to look at them. I had not known it was my eyes that our daughter thought I should be checked for hepatitis. [Later in the year I sat in a room with 8 ladies, 6 of which had hepatitis that year.]

Allergy test at Century showed at that time only two foods fell in the "Eat all you want" list, catfish and asparagus, had to go to the next group. You were to add a little of the next group one at a time and let the body adjust before adding another. Don't think they had a case like mine before.

I was thrilled to be feeling better and know what I could do to keep improving my health. I told everyone about the dermatron machine.

1990 September the FDA raided the Century Clinic in Reno, Nevada, a clinic specializing in nutritional medicine, seizing over $50,000 worth of medical equipment, including the dermatron machine. When no charges were filed, Dr. Tang sued for the return of the property, the FDA raided again. This time they confiscated over $60,000 of clinical property and $10,000 cash.

Office manager was stripped completely naked and Dr. C was stripped to her underwear and searched. Patient records were seized, patients were interrogated about the nature of their illnesses, as well as about the type of therapy they were receiving. They were told if they chose to continue receiving treatment, they would be attended by a physician provided by the FDA. This included one patient, who's husband, an M.D. was present at her side, supporting her treatment. They stopped treatments by taking the needles out of the patients arms!

This kind of treatment burns me up! Taking patients records is unconstitutional. It is also unconstitutional to seize property without cause.

This kind of search is an outrage to our decency and rights as citizens of this country and we need to get rid of the head of the FDA for doing such. No head of a government agency should be allowed in office with these tactics. No wonder people loose confidence in our officials.

Because of my visit at Century Clinic I was able to know what to do to help my body. I started reading in depth everything I could find on how to cleansed the lymph system. I have learned many things by observing my body reactions. I now weigh between 104 and 108 lbs. I was able to go off heart and thyroid medicine and now I take no drugs.

In cleansing out the lymph system I have almost completely gotten rid of the accumulation of trash that pocketed in the glands in my armpits. In one session of cleansing I had the place that showed up in the mammogram in my breast, disappear. I am still cleansing out the lymph system. It didn't get all clogged up overnight, and it takes time to reverse the process. A blood allergy test showed my allergies are now only 20% and a good part of these are some kind of seasoning, not foods.

Liver scan at South Community Hospital	$225.50
Interpretation of imaging	$ 65.00
Dermatron test	$150.00
Injection	$ 50.00

But it was not really cheaper for I had to pay the air fare and hotel. This service should be available nationwide and we should have the choice even in hospitals what kind of treatment we prefer; Allopathic which was the alternative care in the early 1800's or the Natural Healing which was the mainstream practice in the early 1800's, but which is reversed today.

STATEMENT OF ALICE ALIBRIO

I urge you to co-sponsor and vote for S.2140, The Access to Medical Treatment Act.

I hold a Bachelor of Art's degree in Philosophy and Art, and a Master's Degree in Social Work. I worked for six years in child abuse in Massachusetts. Since moving to Santa Cruz, California, I completed an Herbal Apprentice program and I continue to study natural healing. I am currently employed as a substitute and daycare teacher at the Montessori school and as a clerk in a dietary supplement store. I am enrolled in a community college for pre-medical requirements. I plan to attend Naturopathic school, another four years of intense study, to obtain a Naturopathic doctorate degree.

My motivation to learn and promote wholistic, natural healing comes from years of witnessing and experiencing Allopathic medicine's often ineffective, dangerous, and expensive treatments. a completely healed back. I was able to stand straighter and breathe easier than when I was a small child. I wrote a letter of complaint to Kaiser Permanente and the director responded Chiropractic care was controversial amongst the doctors, thus, it was not a part of their plan. Patients less determined than I to achieve quality health become the victums of idealogical bigotry.

Shortly after moving to Santa Cruz I developed asthma.. I did not have a medical plan (and I still do not). My asthma was triggered by stress, lack of rest, sulfites, dust, animal dander, and mold. I learned family members also suffered from allergies to dust, animal dander and mold and allergy induced asthma. They were told by conventional doctors that their condition was a genetic fault that required a lifetime course of doctor prescribed medication. I refused this treatment because it was expensive, it would not help me to heal and it had terrible side affects,

such as, nasal tissue and adrenal gland damage. Although I realized asthma can be life threatening, I decided to treat myself, because there were few wholistic practitioners. I modified my diet to strict vegetarian with whole, organic and alkalizing foods to build my immune system and to reduce mucus. I avoided sulfites a common preservative. (I am aware that the F.D.A. has received more letters of complaint from adverse affects to sulfites than any other preservatives, yet it continues to be in the marketplace.) I eliminated, as much as possible, lack of rest and stress. Asthma can be a frightening experience and if the mind runs rampant with panic the attack is worsened. I used my Vipassana meditation practice to keep calm. The key to my successful self treatment are two native California medicinal plants which strengthen the lungs, dry excess mucus, and are anti-spasmodic. I took an herbal preparation with these two herbs as the primary ingredients whenever I felt the onset of

Every year between 60,000 and 120,000 Americans die from prescription drugs. Allopathic medicine is much more dangerous and far less effective than we have been led to believe. Its' limitations as well as its' assets needs to be recognized. Surgery techniques and emergency care has vastly improved over the years. Unfortunately, Allopathic medicine through political manipulation has monopolized medicine and has allowed profit to pervert health care into sickness care. We need to open the doors to safer, less expensive methodologies that promote health. Imagine what a progressive and complimentary health care system we could have if natural, wholistic medicine was routinely used to both treat and prevent chronic, degenerative disease.

There is a growing abundance of scientific evidence proving the efficacy of natural treatments. I have included a bibliography of some excellent natural healing writings. Please read on. Thank-you for your time.

STATEMENT OF ELISSA MEININGER

As you and your colleagues deliberate *The Access To Medical Treatment Act of 1994 (S 2140)*, please be aware that for many of us the purpose of this bill is not just to limit the authority of a government agency. It is to put a stop to the systematic suppression of non-mainstream medical practices which many of us rely on for our daily survival

In my own case, I was plagued for many years with the symptoms of mercury poisoning (memory loss, fatigue, hyperactivity, metabolic and digestive problems) which mainstream physicians had no way of properly diagnosing. At the point when I was no longer able to get out of bed or carry on a coherent conversation, I turned in desperation to the only Homeopathic physician I could find

He not only diagnosed and cured my illness — he pointed out, among other things, that the symptoms of mercury poisoning had been understood by Homeopaths the world over for many generations, but that the war waged against Homeopathy by mainstream physicians and the proprietary drug industry in this country had been so successful, few Homeopaths remained to diagnose it. Many Americans are not as lucky as I was. Homeopaths are hard to find, their skills are not widely publicized, and they work in constant fear of harassment from state and federal authorities. Yet, the fact remains that after years of mainstream failure, a Homeopath diagnosed and cured my illness

For me, the bottom line for supporting passage of *The Access To Medical Treatment Act* is the fact that we, the public, are still being held hostage to this age-old philosophical fight between mainstream (Allopathic) medicine and Homeopathic medicine. (Around the world, mainstream American medicine is called Allopathy, as opposed to Homeopathy, which is based on a different set of medical principles.) Currently, all government medical policy decisions are being made based on the mainstream Allopathic medical model. So complete is the government's commitment to this single view of medical thought, that anyone who even suggests limitations to this medical model, no matter how learned or respected, is severely ostracized. Given this climate, few dare risk speaking out, and in this conspiracy of silence, millions of people like me are denied access to appropriate non-Allopathic medical care.

The most vivid example of this systematic denial of other philosophical medical truths involves the dispute over mercury poisoning, which still remains a hot issue. In 1991, the FDA held hearings on the possible dangers of silver-mercury dental fillings. These hearings should have provided a major opportunity for our government to at long last properly address this ongoing dental community fight. (As you may know, there are 180 million Americans with mercury in their teeth, and thousands of reported cases of dental-related mercury poisoning.) But because the FDA relies for advice mainly upon Allopaths, and not Homeopaths, Naturopaths, or representatives of any other alternative medical philosophy now emerging from other parts of the world, the only conclusion they were able to draw was the fairly pitiful and predictable one that the subject needed additional study.

I have included with this letter some startling references dating as far back to 1807, illustrating the fact that for generations, scores of mercury experts have argued with the Allopathic community over the entire issue of the use of mercury in medicine. (You will note that most of these references, starting with a quote from Thomas Jefferson, deal not with the fact that Allopaths were unable to diagnose mercury poisoning, but that they were actually using mercury-based treatment to exacerbate existing illnesses, and in the case of George Washington, probably causing his death.) Amazingly, the Allopathic community has consistently failed to listen and it is very likely that many Americans have died as a result. This material will also give you a flavor of the deeper philosophical argument that exists between Allopaths and non-Allopaths – something we all need to understand as we deliberate all issues surrounding health care reform.

[Additional material is retained in the files of the committee.]

STATEMENT OF LORI EVERHART

Senator Harkin and members of the Senate Labor and Human Resources Committee, my name is Lori Everhart and I am the Executive Director of Kentucky Citizen Action. I appreciate the opportunity to enter my written testimony into the hearing record of S.2140, The Access to Medical Treatment Act, held on July 22, 1994.

Citizen Action is a national nonprofit, nonpartisan grassroots consumer rights organization with over 3 million members throughout the United States. We are an educational and advocacy organization working with low and moderate income people to achieve social and economic justice at the local and state levels. As such an organization, we have been active in all aspects of the health care debate for the past ten years. In the state of Kentucky, as in other states, we provide organizing, research, training and networking support for a coalition of grassroots organizations working on health care issues including senior citizen, worker, minority and citizens organizations.

I respectfully enter this testimony today on behalf of our Kentucky Citizens Fund Patients' Rights Project. Through our activity with this project and our active participation for the past ten years in the health care reform debate, we have found that quality of care and access to various types of care is of primary concern to patients and members of their families. While we are not an organization whose primary advocacy position is on behalf of that of alternative care, we do strongly advocate for the rights of citizens to choose the type of care that they feel best suits their individual needs. In order to make that choice an informed and educated one, however, citizens must be given access to any and all information available about a given procedure or treatment. It is only after being armed with this information, that we as individuals can make that informed decision about what treatment is best for us. And we must then be trusted enough, based upon this open and available access, to decide for ourselves what method of treatment is most appropriate. Many of the problems within the health care system as we know it today have directly resulted from too little input from the individual with regards to their own care. This point has been brought to light time and again throughout the current health care debate and should be taken into consideration within the context of this proposed legislation as well. If we as citizens truly do need to take more responsibility for our own care, then we must be given access to information on various types of care, as well as the ability to directly access those various types of care. Only then will we be able to work with our health care providers to determine what is best for our own lives and our own well-being.

I urge you to support various methods of health care treatment and access to information on those methods within your consideration of S.2140. Thank you again for the opportunity to submit this testimony and for your consideration of this legislation.

Statement of Dr. Ted Rozema

If we are to provide a health care system that will reduce the cost to the payer as well as provide a markedly less invasive therapy for vascular disease, we must include a therapy that has stood the test of time, producing marked improvement in patients with severe circulation problems even though it has not had the impromptur of the "scientific " community. I realize this will mean changes in a segment of the established surgical arena, but a positive change is always good if it can relieve suffering at a lower cost than that already in use.

Chelation therapy with EDTA, (Ethylene Diamine Tetraacetic Acid) for vascular disease has been occurring in this country since the early 1950's. Medical literature published in that era demonstrated reduction of calcium in heart valves in patients undergoing this therapy. Angina pain was relieved and enthusiasm was high.

However, coronary bypass surgery for myocardial blockage began around 1964 and after Abbott Laboratories lost their patent rights to the compound in 1968, research dried up and this therapy fell through the cracks. However, there are physicians who have been using this EDTA therapy since 1962 who continue to reduce the need for high cost surgical intervention with the use of this, now considered alternative, therapy.

Experience in another country with a socialized health care system demonstrates that patients waiting for surgery for bypass or amputation were able to forgo the surgery with the use of EDTA chelation therapy. The Danish study by Dr.'s Hancke and Flutie published in the Journal of Advancement of Medicine, 1993, demonstrated that 58 out of 65 patients on the waiting list for bypass surgery were able to cancel and not require the surgery after receiving EDTA chelation therapy. 24 out of 27 patients on the list for amputations were also able to cancel their surgery after the same non-invasive treatment.

According to this data, EDTA chelation therapy might have prevented 363,000 of the 407,000 bypass procedures done in the U.S. in 1991, a savings of more than $8 Billion dollars.

Early on, the FDA did have the use of EDTA for vascular disease, an already approved drug, branded as quackery. However, this designation has been removed

and any comment to the contrary will be using outdated material. Most physicians routinely use approved drugs for "off-label" uses. Perhaps the best example of this is the use of Persantine to "help blood flow better", as described by internists and cardiologists.

Dr. Ray Evers, in his running battle with the FDA, did get the FDA to acknowledge that any drug can be used for anything the physician deems useful once it has been certified by the FDA for safety and efficacy in at least one application. If Physicians did not have this latitude, many of the drugs on the market today would not be used for their present applications that are different from those initially certified. Observations by intelligent physicians have led to changes in medical drug use, but history teaches that this is a slow and painful process. This is now the time to be including chelation therapy for vascular disease into main stream medicine.

My personal experience with EDTA chelation therapy for vascular disease over the past 11 years has borne out the positive reversal of vascular disease in patients facing either bypass surgery or amputation. Initially I was quite skeptical, as I had not been taught this therapy during my medical education at Northwestern University in Chicago, Illinois. However, clinical use soon removed my skepticism. I am delighted to say we have greatly reduced the need for surgical intervention with it's resultant death and morbidity in the great majority of our patients.

I was instrumental in creating the International Chelation Research Foundation that produced an FDA approved double blind study on the "use of magnesium disodium EDTA for peripheral vascular disease" at Walter. Reed Army Hospital. However, "Desert Storm" put a severe crimp in this effort (which should be reactivated), as it is now in a hold position due to lack of funds

Because of the concerns about safety and the need to have properly trained physicians administering the therapy, the American College of Advancement in Medicine and the Great Lakes Association of Clinical Medicine hold educational workshops and symposia. There have been over 2000 physicians trained over the past 13 years. I have been a lecturer in these training programs for the past eight years and can attest to the scientific body of knowledge provided. Regardless of claims made to the contrary, there is a tremendous volume of scientific literature to back up the claims made by it's advocates. However this literature is not readily available to most investigators as much was produced before the standard medical search systems were created.

It strikes me as odd that there is so much negative press about EDTA chelation therapy from the "establishment" but not from the hundreds of thousands of patients treated with this therapy. There is a peculiar circuitous method used to quote from other's damming comments. It's almost like creating validity of one's arguments by saying what your friend said about what your friend said. This is the system used by the American Heart Association to say what the American Medical Association says about what the American College of Cardiology says about what the American Heart Association said. This certainly detracts from the meat of the matter, that patients are improving with EDTA chelation therapy regardless what the naysayors are preaching. Me thinks their ox is being gored and it hurts.!

Please take a long hard look into this therapy as it fits so well into the charge you have been given. It reduces the need for much more expensive therapies, it cuts down on pharmaceutical drug usage, it promotes better health to the living human organism, and restores vigor and vitality. It is not a panacea, but a useful medical treatment for those with vascular and degenerative diseases.

STATEMENT OF LYDIA D. KRESS

In the interest of time, this will be brief. I hope this will in no way diminish its validity. Two years ago I woke up each morning completely exhausted, my entire body wracked with pain, to face a day of confusion, dizziness, hopelessness, struggling to breathe, and living on pain-killers 24 hours a day. Getting out of bed was an effort which drained me completely and, more often then not, if I was not assisted by my husband, I would faint. None of the several doctors I consulted during this miserable period of my life was able to correctly diagnose or treat my illness. It seemed to me, all I could look forward to in the future was a life of continual pain, confined to bed, living on pain-killers, unable to do even the simplest of tasks.

Eventually, because of a series of fortunate events, which resulted in my case being referred to a reputable pain prevention clinic in Palm Springs, California, which specialized in chelation therapy, my participation in its chelation therapy program began. At first, I was afraid. If the treatments did not help me, I would have to cope with disappointment and hopelessness again. As I observed other patients in the same room with me, some of them needed assistance in walking. One elderly woman, in particular, was wheeled in,by her care=giver, in a wheelchair. A little later in the program she no longer needed a wheel-chair, but instead used a walker, to be

replaced later by a cane. The last time I saw her, she was walking without even a cane, with no assistance, but with a firm step and a look of confidence on her face. All of this took place within a 6-week period of time.

In the meantime, I noticed I was able to cut back on paint-killers. As the chelation flushed the toxins out of my system, I began to require less sleep. I could be in my feet for several hours at a time. I could do a few simple tasks I had to do. I could go shopping at the market with my husband. I could read a line of print and remember what I had read, without reading it twice. At last, I was getting better gradually. Finally, now I can look forward to spending my remaining years doing things I want to do. This would have been impossible without chelation therapy.

I hope the members of the U. S. Senate Labor and Human Resources Committee will find that Chelation Therapy is an important and necessary treatment in our current health care programs. Its benefits include elimination of costly hospital and convalescent home bills, shortened periods of recuperation after illness, as well as the restoration of happy, productive and active lives. Furthermore, Medicaid, Medicare and insurance companies would see a reduction in their costs.

STATEMENT OF EDWARD R. SITZLER

I am a 73 year old American Citizen. I started work after high school in 1939, with the exception of my navy service, I have worked ever since.

Today I am C.E.O. of a successful small business that employs approximately 125 people. When I began my career we had no medical insurance. If you were sick you paid your Doctor just like the grocer. People were responsible for themselves, they were not looking for government to take care of them. I still believe we are responsible for ourselves. I believe our constitution guarantees us the right to the pursuit of freedom, health, happiness, etc.

As regards medical treatment, I am diabetic and have had several operations. The best thing that happened to me was being born in the United States. A person could not have better care than we have in this country. Is it too costly - perhaps - are mistakes made - certainly!, we all make mistakes, that's life! THATS why I want my freedom to choose.

Freedom to choose where I live where I work, my Doctor, my health care.

Please do not limit our freedom to pursue medical treatment regardless of its acceptance by others. If a doctor can give and will give a person a treatment that that person wants then it should be allowed.

At present I am taking Chelation for circulation in my legs, due to diabetes. It is helping my situation. I have talked with others that have saved their legs from amputation by taking Chelation.

The medical association in Kentucky is against this procedure. They have closed down several doctors. They may close the last doctor by voiding his License. This is wrong! This is against our freedom to choose.

Senator the bottom line is Please don't prohibit the citizens the freedom to choose in a country that is built on freedom.

Statement of Lt. Col. John A. Campbell

I am 71 and I retired from the Army in 1972 after 28 years of service. I worked for the Army at Fort Knox, Kentucky as Director of the Patton Museum of Armor for 10 years following military retirement and have worked as a volunteer with the Museum's Foundation since leaving the Director's position.

I am a Chelation patient and submit the following regarding my experience with this program:

In July 1993, I visited my cardiologist regarding minor chest pains I was experiencing. Two years earlier it was determined I had a heart murmur and this was diagnosed as the probable reason for my shortness of breath and chest pains during periods of physical activity. However, the pain had become a little more pronounced in July 1993.

The cardiologist advised that I take a treadmill stress test. This was accomplished in October 1993 and the result was I had blockage in the artery or arteries supplying blood to the muscles in the back of my heart.

To compensate for the lack of blood supply to these muscles, a treatment of medicine was recommended and started in October (1993). The results were not satisfactory to me. No relief was noticed in my physical condition plus my mental state caused by the medicine, Atenolol, was totally unacceptable.

My cardiologist, during the October visits had indicated that should the medication not accomplish the desired results we could take other steps to relieve the blockage. He did not suggest bypass surgery or angioplasty nor did I question him on this possibility. My wife was with me during this visit of October 26.

Since I had known of Chelation for several years, my wife (an R.N.) and I took the necessary action to locate a doctor in our area who provided Chelation.

I arranged for an appointment with a doctor in Prospect, Kentucky and visited him on 30 November 1993. I was given an extensive physical examination which included a stress test. Again, it was determined I had blockage in the heart muscle arteries. The doctor talked to me at great length about the Chelation program to insure both himself and me that I thoroughly understood the program.

I have, to the best of my ability, followed his advice on diet, vitamins, minerals and in general, life style.

I started my Chelation treatment on 14 December 1993. The first treatment was an infusion of selected minerals that a previous test revealed my system required. The first Ethylene Diamine Tetraacetic Acid (EDTA) treatment was received on 11 January 1994. My 29th EDTA treatment on 26 July 1994.

I have maintained a rather detailed account of each visit. This includes the time treatment began, when completed, who administered the treatment and my physical reaction during each treatment. I am aware of the weak and strong point of this treatment.

I play golf, sometimes walking, sometimes riding in a cart and use a push mower to cut my lawn which requires about eight hours a week to accomplish. These activities have produced various physical conditions ranging from minor to rather pronounced fatigue. Each of these conditions, to include date and time, are in my notes.

Following the first several EDTA treatments, very little, if any improvement was evident in my physical capabilities and I was waiting for what I hoped for and was reasonably certain would happen. Both my wife and I have read extensively on Chelation and continued to caution each other to be patient. Following the twenty-first and twenty-second treatment, I could definitely and confidently assure my wife it was working. I could feel a change.

During the past weeks in the period of my twenty-sixth, seventh, eighth, and ninth treatments, I have mowed grass for two and three hours in rather hot weather and experienced only slight chest pains. Work in my yard and garden during the weeks of 4 and 11 July was accomplished without chest pain and with only moderate fatigue.

My program is forty EDTA treatments and five mineral build-up sessions. This will be followed by periodic maintenance infusions. As indicated above, I have received twenty-nine EDTA treatments and three mineral build-ups.

My physical condition and my confidence has improved to the degree that I can walk the golf course and mow my lawn and do those other things in life I choose without thinking "don't do this, you may bring on a stroke or severe heart attack." This new outlook I have for life I attribute to Chelation. Chelation treatment has provided me the quality of life I want and which I feel is possible and available through this treatment program.

Should I be forced to undergo surgery to accomplish only a small portion of the benefit I receive from Chelation, is totally unfair and perhaps fatal. To restrict the Chelation program will also deny me a freedom of choice of medical treatment.

The expense of this treatment, with the exception of minor and infrequent tests, is paid for by me without cost to any government agency or private insurance firm.

The above is submitted as a true and factual statement and I take full responsibility for my physical condition and fiscal obligations.

If possible, I plan to continue to receive Chelation treatment on a schedule based on my doctor's advice for the remainder of my life. I believe in the program and trust the doctor who administers it in our area.

Statement of Anthony J. Ortner

GENTLEMEN:

MY NAME IS ANTHONY J. ORTNER, A PRACTICING ATTORNEY, OF 700 LIVE OAK STREET, MAITLAND, FLORIDA 32751.

I AM PRESENTLY UNDERGOING MEDICAL TREATMENT FOR SEVERE MALABSORPTION OF THE INTESTINAL TRACT, PERNICIOUS ANEMIA AND GLUTEN INTOLERANCE. THE FOREGOING PROBLEMS REQUIRE SUPPLEMENTING MY DAILY FOOD INTAKE WITH VITAMINS AND MINERALS TAKEN BY MOUTH, AND BY INTRAVENOUS FEEDING.

TRADITIONAL MEDICAL PRACTICE LACKED BOTH THE TRAINING AND INCLINATION TO ADDRESS MY PROBLEMS. AS A LAST RESORT I FORTUNATELY FOUND A SOLUTION IN ALTERNATIVE MEDICINE WITH DR. JOYA L. SCHOEN, M.D., OF MAITLAND, FLORIDA, WHO IS PROVIDING LIFE SAVING NUTRITION BY A WELL PLANNED PROGRAM OF INTRAVENOUS AND ORAL SUPPLEMENTATION. IT HAS BEEN YEARS SINCE I FELT SO GOOD.

VERY SOON I WILL UNDERGO CHELATION THERAPY TO REMOVE THE TOXIC METALS FROM MY BODY TISSUES AND BONES. THESE METALS, DID NOT EXIST IN MY ANCESTORS, AND WHICH I HAVE IN MY TISSUES ARE LEAD, ARSENIC, MERCURY, ALUMINUM AND NICKEL. THE VERY HIGH LEVELS OF ALUMINUM WHICH WERE IDENTIFIED IN MY BODY PRESENT SUBSTANTIAL CONCERN ABOUT A FUTURE INVOLVING ALZHEIMER'S DISEASE. I LOOK TO CHELATION THERAPY AS THE ANSWER TO LIVING A VITAL AND FULL LIFE WITHOUT THE FEAR OF ALZHEIMER'S DISEASE WHICH KILLS 100,000 PEOPLE A YEAR.

IT IS SAD INDEED WHEN THE US GOVERNMENT DOES NOT RECOGNIZE MY DEFICIENCIES AND ILLNESSES. I HAVE BEEN FORCED TO SEARCH OUT A MEDICAL DOCTOR WHO IS WILLING TO TAKE THE TIME AND ENERGY TO ADDRESS NON-CATASTROPHIC AND PREVENTIVE MEDICINE. FORTUNATELY, ALTERNATIVE MEDICINE DOES THE HARD, INGLORIOUS WORK OF SEARCHING OUT THE SUBTLE CLUES AS A SCIENTIST SHOULD. MY HAT IS OFF TO THESE DEDICATED PEOPLE WHO ARE GIVING ME A CHANCE TO BE ALIVE AND VITAL AGAIN.

BESIDES REMOVING THESE DANGEROUS TOXIC SUBSTANCES I HAVE GREAT HOPE THAT THE CHELATION TREATMENTS WILL COMPLEMENT MY NUTRITIONAL NEEDS BY OPENING THE NUMEROUS CAPILLARIES IN MY VEINS AND ARTERIES, THEREBY, PERMITTING NUTRITION TO GET TO THE AREAS WHERE IT IS SORELY NEEDED. MY SITUATION IS URGENT. THESE TWO PROGRAMS OF NUTRITION AND CHELATION, WORKING TOGETHER, WILL MAKE ME A WHOLE PERSON AGAIN.

MEDICARE AND CHAMPUS DO NOT YET RECOGNIZE MY PROBLEMS AND THEIR MEDICAL SOLUTIONS VIA INTENSIVE NUTRITION AND CHELATION THERAPY. THE EXPENSE, ALTHOUGH MODEST COMPARED TO THOSE FOR BY-PASS SURGERY AND ANGIOPLASTY, CAN RUN UPWARDS OF THREE TO FIVE THOUSAND DOLLARS, NOT COVERED BY INSURANCE. ALTERNATIVE MEDICINE SHOULD BE INCLUDED IN ANY NEW HEALTH CARE BILL. I URGE YOUR SUPPORT.

THANK YOU FOR YOUR HELP.

Statement of David L. Carter

Save My Legs

I am a man 70 years of age. (My identity is provided on an addendum page)

I was diagnosed with diabetes in 1987. I was put on oral medication and it was recommended that I take a long walk each day. I tried the walking but found that I could not go very far, only a block or two at a time.

Within a year I was walking two miles a day and continued to do so for almost three years. However, I began to have trouble in 1991. While walking my legs would suddenly go dead; there was no pain, just a lifeless feeling, a numbness in both legs. I had difficulty in moving as I had to watch my feet while walking. That was scary.

I contacted a doctor who used chelation. He recommended a series of treatments which were started at once.

After I had had some 9 or 10 treatments, I started a daily walk. I got about a quarter mile along when all at once I got pains in both legs. It hurt so much I finally had to stop.

I talked to myself: "This is crazy! Why am I taking those treatments? Why am I spending all that money? They're right, those who say it's just quack medicine."

I stood there resting against a tree. Then it hit me: I had pain! Why had I started anyway? Because I had total numbness, and now I had a sensation in both legs. So I went ahead with my walk, both legs hurting something aweful but I was happy with the sensation.

By that time I was a firm believer in chelation.

Unfortunely, I had a setback. In January 1992 my Mother had a stroke, and after two weeks in the hospital, she died. During that time I ate irregularly, ate foods forbidden to me, did not take the medicine regularly, and slept little, After her death I spent much time tending to her affairs, and settling her estate. So for several weeks I had an unhealthy lifestyle with no daily walks. I therefore undertook another series of treatments. Afterwards I went into "maintenance", that is, one treatment each month. I have had to date 90 treatments.

I cannot walk two miles all at once as I did before; I can walk a half mile or so before I get the intermittent claudification. However, both my feet are warm and pink in color which indicates they are receiving enough blood to stay reasonably healthy.

That contrasts with a former coworker whom I heard about the day. He has had part of one leg amputated because of diabetic complications. If only I had known and could have told him about chelation!

Unfortunately, there is no assurance that I can continue to receive the monthly maintenance treatments, Fewer and fewer physicians offer chelation: the medical community discourages it. A doctor risks the displeasure of the medical community and even the loss of his license to practice. At the very least he is the object of much harassment. Evidently, the medical people figure that chelation is a threat to their income because it is effective and could replace more expensive but less effective treatments. It has nothing to do with whether they believe it works or not; it is

Widely rumored that a goodly number give themselves chelation in private while denouncing it in public.

In 1988 or 1989 I attended a Sunday afternoon seminar on diabetes sponsored by the local installation of a national [illegible] firm. The speakers explained that they were ready to assist us as we went blind, to help us as our kidneys failed, or to train us to live after our extremeties were cut off. Not once did any of them mention that there was a treatment which could prevent these calamities.

I now fear that soon the therapy will not be available unless I travel to Mexico or Chile, or someplace like that (which is obviously impractical), unless the treatment is approved so that the doctors who administer it are not hounded out of the community.

For Dogs and Horses Only

July 4, 1991. My 9-year old grandson is playing little league baseball his first year, I go to watch, sit there about an hour in the bleachers. It is getting hot so I decide to leave without watching all the game.

I step down from the bleachers and - Oh my God! what a horrible pain. I collapse on the ground. Someone helps me to stand but I cannot put any weight on my left leg. There is a searing pain in my knee. I walk to the car but it takes me about 25 minutes to go the block.

I drive home without any problem, using my right leg only. Along the way I decide, "Its happened, I must get ready to go to a nursing home. My life is over." Why so sudden? Well, I had had some trouble with that leg for about two years; whenever I stooped then tried to stand, there was a weakness there, and sometimes I had to pull on something to be able to stand. But there had never been any pain before.

Once home I cannot walk at all. I crawl from the car to the house. I go to the bathroom thinking an aspirin or two might help. As I reach on the shelf I see that dark brown bottle at the back, the one with the label saying FOR DOGS OR HORSES ONLY. Idea! Try that. I take a cotton ball, wet it with the clear liquid from the bottle and swab my knee with it , front and back, and side

to side. There is a mild burning sensation and the skin turns pink. I still cannot stand. I crawl to an easy chair , rest my leg on a stool. After 20 minutes or so I remember that I did not get an aspirin. I get up to go for it and then, there is no pain! I can walk.

It did not last long, the pain returned. An hour or so later I used the liquid again. Again the pain was gone. For a week I used it about four times a day, then I started using it but twice a day, and did so until the middle of September. Since then there has been no problem with the knee.

In October I made a scheduled visit to my doctor. I told him how I had used DMSO (Dimethyl Sulfoxide) to cure my knee. He laughed, slapped his knee and said;"Well I'll be! Good for you. I didn't know anyone else but me knew about DMSO."

I asked, "You mean you use it yourself?"

"Yes, of course."

"Do you use it for family?"

"Yes."

"Do you prescribe it for your patients?"

"No! Well,. well maybe once or twice I have."

"Doctor, Why don't you use it on patients?"

"Well, you know, it might not be understood."

I had discovered one use for DMSO. Yet my docter would not have told me about it, or have told anyone else about it.

In "DMSO Natures Healer", Dr. Morton Walker quotes Dr. Stanley w. Jacob as follows: "We've had only three new principles in our century - the antibiotic principle, the cortisone principle, and now the DMSO principle - and the DMSO principle is the only new one of our generation."

I can buy DMSO if I tell the store clerk I have an old dog with a gimpy leg - never mind that the old "dog" is my foot. If I said that I was going to use it for myself, they would not sell it to me.

So, there is this great medicine out there with dozens of marvelous uses, which one can buy at the dog-medicine counter, a drug with its own "principle", but which most doctors will not use on their patients, but will use for their own families. What gives? Well, it is because the drug store does not want to be

raided by the FDA; the doctor does not want to be known as an "alternative" or "holistic" doctor, as he would be ostracized by his fellow doctors. Yet this is a drug that is legal and approved by the FDA.

ADDENDUM

I, the author of this testimony, am David L Carter. I reside at 594 Radcliffe Road, Lexington, KY 40505.

I prefer that identity not be revealed in respect to the Save My legs portion. I have no such reserve as regards the For Dogs and Horses Only experience.

Statement of Violet Gillen

I have been a nurse for over 50 years and have seen and taken care of many patients that do not respond to conventional treatment. I am one of those who has been allergic to all drugs including aspirin. I had to go outside my profession to find help.

Chelation has helped me and I feel that it should be considered one of the most valuable alterntives that are being used today.

Thank you for you "VISION" and consideration for people like me who are alergic to chemicals and suffer the injustice of same.

Statement of Jack W. Hamman

It is virtually impossible to write a complete testimony about chelation therapy that would be both precise and compact. The effectiveness of this treatment for cardio-vascular disease cannot be described with only a few pages of testimony.

In December of 1991, I suffered a stroke, and in April 1992 I had a second stroke. After five months of conventional treatment, my condition had worsened by about 80%. The attending physician suggested that I undergo an endarterectomy, which I refused. Such surgery is risky and offers no more than a band-aid solution to the problem.

My whole family insisted that I explore the possibility of an alternative treatment and through the advice of knowledgeable friends, I sought out Doctor Kirk Morgan in Prospect, Kentucky. I am a retired bio-chemist and when Dr. Morgan gave me the technical book on the process of

chelation therapy, I knew that this would work for me. Chelation therapy using EDTA was my answer. I believe that the formation of plaque in the arteries is a bio-chemical process, and there has to be something to counteract that process. Again, chelation using EDTA is the answer.

Now, the question that has to be addressed is "why was I not told about this treatment and its success rate?" It has been around since the late 1940's. Is it not my right to be told about treatments that are available so that I can make an informed decision?

Chelation therapy using EDTA is not quackery! It is an effective and safe treatment for cardio-vascular disease.

The bills for my hospitalization in 1991 and 1992 were about $40,000 and Medicare and Aetna paid most of them even though I was becoming progressively worse. The first year of chelation therapy cost under $5,000 and now costs me about $600 a year. Neither Medicare nor Aetna will pay for the treatments, even though my condition is constantly improving. Chelation therapy will not repair the damage to my left arm and leg; however, it will reverse the progress of the cardio-vascular disease.

Many times I have been told that there has been no scientific data to back up the successes of EDTA chelation therapy-that the testimonies of over 500,000 people are all anecdotal. By-pass surgery, angioplasty, endarterectomy, coumadin, and channel blockers are all conventional and accepted treatments and also are filled with ancedotal testimonies. These ancedotes are stories of disabilities and death.

The time has come for the medical profession and the insurance companies to consider the welfare of the patient first and to allow him the treatment most effective and not the treatment which guarantees the highest cash return.

I hope that this testimony and the enclosed article will have a major impact on the committee.

STATEMENT OF EDWARD AND SARA NEULING

Edward L Neuling is 69 years of age and Sara E is 67 years and we are both retired.

Edward L: I was disabled by the ravages of rheumatoid arthritis in 1974 when I was only 49 years old. In the past 20 years I have been under the care of Family Physicians, Orthopedic Physicians and Rheumatologists. My medicine has been changed regularly and I believe I have used every drug therapy, old and new, as they are developed. In the past 6 months I began to hear of the Chelation therapy. I have read several books on the subject, talked with people whose health has improved remarkably with Chelation therapy, and have consulted with a Medical Doctor who administers Chelation therapy. I made a decision to use Chelation therapy and I will continue its use. I firmly believe I am making physical improvements.

Sara E: I had heart by-pass surgery in 1983 and on September 1993 I had a second by-pass surgery. In the 10-year interim I had 3 angioplasties. I have followed the recommended diet and exercise program. In the past 6 months I have talked with several people whose circulation has shown marked improvement after taking Chelation therapy

The Senate Labor and Human Resources Committee is holding a hearing on the Access to Medical Treatment Act. As

AMERICAN SENIOR CITIZENS we are asserting our RIGHTS to participate in this public hearing by submitting our statement for the hearing record. Edward L. Nealing served 3 years in the Army in WW II. Both of us are active in the election processes, are active Church members and always in the front with issues concerning all our citizens health and welfare.

We are PLEADING, INSISTING, that Chelation therapy be available for a CHOICE in deciding our health care.

STATEMENT OF GEORGE L. WOLFE

I am a patient in Michigan who receives Alternative Medical Treatment, namely life style modification with I.V. Chelation Therapy. This has helped me and I wish to continue treatment. Please enter this written testimony into the hearing record of S. 2140, The Access to Medical Treatment Act, held on July 22, 1994, so that all Doctors can treat with any method of therapy that is effective and no danger to the patient.

Please understand that this is my desire and that I will be informed about FDA approval or disapproval and will receive prior treatment results from my provider. Please do this and prevent further intrusion by our Government into our private lives. This issue must be forced in our House of Representatives.

Thank you,

STATEMENT OF DOROTHY W. GLASS

I am a 66 year old female and an elected Director to the board of Mission Springs Water District.

My battle with heart disease began at the age of 51 in August of 1979, when I had a heart attack damaging the right atrium. In October of 1979, I underwent a triple coronary bypass.

The surgery was not very successful and my cardiologist a year or so later informed me that my arteries were in too poor of a condition to warrent more surgery.

In January of 1986, I entered UCLA Medical Center for an angiogram to see if anything could be done to help my continuous unstable angina. During that angiogram my heart stopped. I was given electrical shock three (3) times and immediately underwent another coronary bypass surgery. Without a complete angiogram, only the known problem was corrected. This did not relieve severe angina and in April of 1986 I once again underwent bypass surgery. If my memory is correct I have had 8 bypasses. Some to correct other bypasses. I will enclose a copy of my last surgical report.

Since my first surgery I have been careful of my diet and have been through a cardiac rehab program in 1987. After completing the program I purchased a cardiac rehab video tape and have used that and a treadmill for my exercise routine.

In March of 1991, I again started having more arrythmia and severe angina and underwent angioplasty on my left descending coronary artery.

In early 1994, I began to have symptoms again, arrythmia, angina at night if I ate too late or too heavy and with exercise. Also in early June of 1994 I began to have mini strokes.

One of my daughters had tried for years to get me to look into chelation. How I regret that I did not listen sooner. After two or three TIA's (mini strokes) in early June my husband and I went to see Dr. Sean Degnan. What I heard from him and his patients, whom I was allowed to speak to freely, sounded too good to be true. I had already decided that I would never again undergo heart surgery.

I have now had 20 treatments. No more angina, I have more energy and I am able to sleep with only one pillow. Since 1979 I have had to use 2 or 3 pillows. If I slipped off, I would wake because of angina.

I'm still exercising and watching my diet. I am scheduled for 40 treatments and I am anxious to see the results then!

I know that Dr. Degnan had special training in giving chelation and I believe any doctor who gives it sould also have that training.

I have relatives and friends who have diabetes and heart problems that I have seen chelation correct in others, but since chelation is not covered by their insurance they must just ive with their condition. Don't make them go through what I have been through unnecessarilly.

Chelation is a much less painful and much less expensive alternative than bypass surgery.

Please give Chelation approval so this wonderful help can become available to more people. At the same time it will save Medicare unbelievable amounts of money!

Statement of Nellie A. Peters

In 1989 I was having Angina Pains and was unable to walk twenty to thirty feet without having to stop. I was on the verge of having to have a by-pass operation. I was also having trouble keeping my diabetes under control. I had heard about Chelation therapy so I began finding and talking to persons who had had it. I was so impressed by the stories I heard that I decided to try it. By the end of three months I could walk two miles without getting chest pains and my diabetes became more manageable. I had thirty treatments with Dr. Walt Stoll in Lexington, Kentucky. He had a prosperous clinic there. Then the Kentucky Medical Licensure board went after him. It ruined him both financially and his practice. He tried doing everything they asked except to stop giving Chelation therapy and treating patients holistically but the Licensure board continued until he lost his license to practice medicine. He was a doctor who cared for his patients and found ways to treat them without causing them harm. This Medical board has harressed other doctors who do alternative treatment and several have stopped so they won't be brought before the board who is so biased the doctors can't get a fair hearing. After Dr. Stoll was unable to continue Chelation therapy, I found that Dr. Kirk Morgan of Prospect, Kentucky was doing this kind of treatment so I began the treatments and am still taking maintenance.

Since taking Chelation I have seen many miracles. I have seen patients who have had two or three heart by-pass operations and was told there was nothing more could be done for them. They were told to go home, take their medicine, be careful what they do. In other words "go home and wait to die". These patients found out about Chelation therapy and have had their lives extended with a brighter outlook on life. Consider the number of patients whose lives are snuffed out because they were not made aware that Chelation is a choice they could have if they were informed. Often, if they find out about Chelation and ask their conventional doctor, they are told "don't do that, it's dangerous". These doctors often know nothing or very little about it and don't want to

find out. I know because I have asked some conventional doctors this question. I have seen patients that had to be carried into Dr. Stoll's and Dr. Morgan's office who, in a few weeks, are able to walk in without help. The ones who sit on these Medical Licensure boards are so brain-washed they do not want to listen with open minds. I want the right to choose my own doctors and be able to choose alternative treatment. The passing of this bill will give everyone that right and doctors who give this treatment will not live with the fear of having their license revoked.

Statement of Mabel Hostetler

In September, 1990 my family and I were devastated by the news from my family internist and hemotologist. My platlet count was up to 1.2 million. For five years I had been following everything they told me to do. Now they decided I needed chemotherapy! I wasn't willing to accept that. I didn't know how long I must do this or what it would do to my body. I was at the point of no return, or so I thought. I prayed because I wanted to live to raise my daughter. Within one month I was so weak I could hardly get out of bed to go to the bathroom. We were searching for an alternative to this prognosis. Since I had worked in a hospital for 18 years as Controller, I knew there were alternatives. Finally, we heard of this doctor, within twenty miles of our home, who possibly would be able to work with us. My husband had to make three appointments before I was able to get to his office. After the first treatment I felt so much better I knew this was the way to go. Dr. Kirk Morgan, my doctor, has his own Family Clinic. He is a very qualified physician. Almost immediately my platlet count went down to 675,000. I now lead an ordinary life for a 67 year old person.

I came out of retirement to help my husband run our business in real estate. My daughter is 19 years old, a sophmore in college and married. Last year when she wanted to marry her childhood sweetheart, we planned an out door wedding for 150 guests. Seeing her walk down the aisle was one of the happiest days of my life. Now I am looking forward to seeing and helping with my grandchildren. I feel I'm alive because of the Chelation treatments I received from Dr. Morgan. Finding a physician with the sense to look beyond drugs with many side effects was a miracle. I want to be able to continue having these treatments as well as the right to choose other alternative medical care that I may feel I

need in the future. The passage of this legislation is vital to my life and many others.

Statement of Henry and Elsa Ellis

This letter relates to our personal experience with ***Chelation Therapy***, an alternative treatment for heart disease and circulatory problems. Please enter our written testimony, as follows, into the hearing record of S.2140, The Access to Medical Treatment Act, held on July 22, 1994, in support of ***Chelation Therapy*** as an acceptable preventive and alternative non-invasive treatment to be covered by Medicare, Medicaid and private insurance.

Henry's personal experience with ***Chelation Therapy***, is only ***one*** example of case histories in ***Chelation Therapists***' files that are replete with records of patients whose conditions ***have been reversed by Chelation Therapy*** -- patients whose vascular surgeons and cardiologists had diagnosed their blocked arteries as progressive and irreversible. All referrals to ***Chelation Therapists*** are made by satisfied patients who have nothing to gain other than the knowledge that sharing their own experience might save another person's life.

Chelation Therapy involves a painless intravenous drip which circulates throughout the entire body with chemicals to which plaque adheres and discharges through the kidneys (initially used to treat lead poisoning). This treatment helps clear even the smallest, inaccessible blood vessels of plaque. The only potential danger is to patients with kidney problems, which the ***Chelation Therapist*** watches closely.

Chelation Therapists are certified, licensed medical doctors with additional training in chelation therapy.

In spite of the high success record of ***Chelation Therapy*** provided in patients' files, the AMA claims ***Chelation Therapy*** has not undergone adequate "rigorous research and testing" and refuses to let its members recommend ***Chelation Therapy*** -- even for "irreversible" clogged arteries for which regular medical doctors, vascular surgeons and cardiologists can offer no hope or treatment.

Ironically, AMA approves and even recommends invasive, expensive surgery which has never been subjected to "adequate rigorous research and testing" -- by-pass surgery, angioplasty and the new "wire loop" treatment -- procedures, all of which involve a recognized potential danger to the patient and admittedly offer only temporary relief, leaving inoperable blood vessels (e.g., in the brain) untreated.

As a result of the dictatorial, intransigent use of AMA's power

- Doctors are forbidden to recommend ***Chelation Therapy*** as an alternative, preventive treatment -- a situation which seems to be an unforgivable violation of their "Hippocratic oath."
- Patients only learn of this option by word of mouth from other patients; must undergo ***Chelation Therapy against*** the advice of their physician; and must bear the entire cost, which is not reimbursable by Medicare, Medicaid or most insurance companies because it is not approved by AMA.
- This alternative, preventive treatment is denied citizens who are financially dependent upon medical insurance, and whose doctors either refuse to refer patients "because AMA does not approve" or who do not know about the benefits of ***Chelation Therapy***.

We submit that to deny access to ***Chelation Therapy*** is a crime against citizens who are unaware of or cannot afford to pay for ***Chelation Therapy*** and therefore suffer and die prematurely under the present situation. If we are planning to make alternative, preventive treatment available to citizens, ***Chelation Therapy*** must be included as a viable option under the Access to Medical Treatment Act S.2140, and be covered by Medicare, Medicaid and private insurance

Had ***Chelation Therapy*** been offered after Henry's first mild stroke in April 1978, we have every reason to believe his paralysis and later threat to life, and the ***tremendous cost to Medicare*** would have been avoided

Henry suffered his first mild stroke April 1978 which temporarily affected his speech. The next month he was hospitalized with a more serious stroke. The last stroke, in June 1978, paralyzed his left side. It was three years before he could drive again

March 1987, angina and emergency quadruple by-pass Attending doctors said they seldom had a chance to operate on such a severe blockage to a main artery -- patients ***seldom arrived alive!***

December 1989, he was ***cold!*** -- wool socks, heating pad, could not get warm. His color, grey A 30' walk caused excruciating pain in his right calf. Dx. blocked arteries with no pulse in right foot or hand. Arteriogram also revealed blockage of small vessels to the brain. He had voluntarily stopped driving for several months because his reaction was too slow. Vascular surgeon prescribed Trental to make the blood slippery, but said there was nothing else he could do and Henry would have to wait until gangrene set in and then amputate his badly blocked right leg.

In January 1990, Henry started ***Chelation Therapy***, even though his vascular surgeon said he could not advise it because it was not approved by AMA -- but admitted he had nothing better to offer Within a couple of weeks Henry became warm, his color returned, and his leg pains gradually diminished until he was able to walk a mile, sometimes without any leg pain. It was soon apparent to us that the vessels in his brain were also being cleared up Everyone remarked about how much better he looked, he picked up energy and ambition and gradually started driving again His vascular surgeon and cardiologist saw him every six months and their clinical evaluation showed steady progress with circulation returning -- no further mention of amputation! As of June 1994 Henry only goes back for evaluation once a year. He drives with confidence, even in heavy traffic and on long trips. ***The condition had reversed with Chelation Therapy.***

Henry's Testimony: Before I started ***Chelation Therapy*** I felt I did not have long to live I had a family history of poor circulation, strokes and heart attacks: my mother died at the age of 70 of "hardening of the arteries" and three brothers died of stroke or heart attack. Under ***Chelation Therapy*** I have confidently passed age 81 and look forward to the turn of the century and to see my two grandchildren (ages 7 and 5) grow into youths!!! My complexion is a healthy and bright rose I have energy and ambition. I drive alone in and around Orlando. I do my share of Interstate driving on our extended trips across the southeastern states. I can do chores around the house and am independent of any help. Had I ***not taken Chelation Therapy*** I would probably not be here to testify to its great benefits

If you wish to verify Henry's experience with ***Chelation Therapy***, his ***Chelation*** Therapist is Joya Lynn Schoen, M.D., 341 N. Maitland Ave., Maitland, FL 32751 (407)644-2729. His vascular surgeon is Kendricks G. Adcock, M.D., 400 S Maitland Ave., Maitland, FL 32751 (407)539-2100.

We write not for ourselves but for the thousands of our citizens who could benefit by ***Chelation Therapy*** if it were made a recognized procedure in the practice of medicine in the United States so it could be considered to be a procedure of choice when considering the alternatives in heart and circulation. Please enter this written testimony into the hearing record of S.2140, The Access to Medical Treatment Act, before the US Senate Labor and Human Resources Committee July 22, 1994

Statement of Albert L. Jamison

I want to strongly recommend that Chelation Therapy be included in the alternative treatments made available to the general public and eliminate the powerful Medical establishment's self-serving methods that crushes anything that threatens their wallet. There are many Doctors that would like to use alternative therapy like Chelation Therapy or at least recommend it but are held back by the threats and fear of being torn apart by their medical peers. Allowing the medical establishment to be the supreme guide to approving any new therapy, especially a simpler and cheaper one, is like making the fox the security guard for the hen house.

My wife and I are very fortunate to live in Southern California where some very courageous doctors have made Chelation Therapy both available, and affordable. My wife and I are having Chelation Therapy as a preventative measure and have been pleasantly surprised to have received several beneficial side benefits. I am 66 years old, my wife 64 and we are in good general health. However, I do have a mild heart arrhythmia that I have had since early youth. The treatments have lessened its effects. In addition the improved blood flow, produced by the Chelation Therapy, has made my skin, and my wife's, softer and more youthful. No, we haven't turned our faces back ten years, but the extra blood flow has increased our energy level, at our age that is a definite plus.

During our Chelation Therapy, a lady came all the way from Rhode Island to have Chelation Therapy at the same clinic where we're having ours. She could hardly walk across the room unassisted. Her Doctors were insisting that she have by- pass surgery. Fortunately her son, who lives in Southern California, persuaded her to consider an alternative treatment first. He researched Chelation Therapy and our Doctor in particular and chose him to perform the Chelation Therapy. We watched with our own eyes the transformation take place. After approximately twenty treatments her color has come back along with her short term memory. Her energy level has increased until she can walk all around the Doctor's office and do some exercise walking. She was also diabetic and has been able to reduce her insulin intake dramatically, that after 20 or more years of requiring ever larger doses. I think is is criminal what the established medical profession is being allowed to get away with in suppressing this life saving treatment, and many other beneficial techniques.

I would like to recommend a book that does a very thorough job of cataloging the benefits of Chelation Therapy. The book is titled "FORTY SOMETHING FOREVER" by Harold & Arline Brecher and published by Healthsavers Press ISBN 0927839-46-6 Anyone seriously considering Chelation can have all their questions answered by this publication.

Statement of S.J. Renn

This letter is to urge you to support Bill #S2140.

We do need alternative medicines. Here is what it has done for me. I nave had about 27 Chelation Treatments. Before I took these treatments, I always had soreness in my cnest. Four doctors, including my Cardiologist, could not tell me wny

or what would cure it. The only treatment they said was to take aspirin or tylenol.

I had been bothered with this since I had two heart attacks about ten years ago. I also had bouts of severe arrhythmia and since my Chelation treatments in May, 1993 through about September, 1993, my arrhythmia has decreased dramatically. I have had no more soreness in my chest and am on two thirds of my usual heart medication.

It seems strange that our country thinks more of funding abortions than it does preventive medicine. Europe has it. Why can't we? Do the drug companies control the FDA? It seems that way to me.

In any case, I am asking you to support this Bill. Our country needs someone who will stand up and speak out.

Thank you for your attention in this very serious matter.

Statement of James Pooler

I pray you will make EDTA Chelation Therapy and H2O2 Infusions an acceptable medical treatment in America and have those treatments paid for by Medicaid/Medicare and all health insurance companies. EDTA Chelation Therapy saved my life after all other "approved" therapies failed.

In 1984 I had my first heart attack. Shortly thereafter I had my first angioplasty which lasted two years. Then I had four more angioplasty treatments three months apart. I then had open heart surgery.

By July of 1993 I was in deep trouble again and could not walk up one flight of stairs without having to take nitro pills.

Finally, in August 1993, after calling all over the country, I located an EDTA Chelation Therapy clinic in Cambridge, Massachusetts. For the next few months I commuted four hours

one way, twice a week to get treatments. I knew after the eight treatments they were helping me.

By February 1994, I was able to obtain treatments in Waterville, Maine which is only one hour from home. Because of these treatments I am productive, operating my dry cleaning business, instead of being a burden on society by drawing on my social security.

To date, I have had about 40 treatments at a cost of about $4,000-$5,000 vs. the tens of thousands of dollars my insurance company and I spent on treatments which did not work. Not making this treatment available to the general public, paid for by the insurance carriers and Medicare/Medicaid I believe is criminal.

While having my 3 hour infusions I have met many wonderful people and witnessed miracle recoveries from diabetes to heart disease.
The doctor's code is "First do thee no harm". In my opinion, the doctors operating first, before using EDTA Chelation, are breaking their own code. I believe it because they can make more money fast by operating. Most chelation doctors will tell you open heart surgery is only needed in 20% of artery blockages.
I understand the country of New Zealand requires all heart patients with artery blockage to have Chelation Therapy prior to having open heart surgery.
Please make sure these treatments are available to all Americans.

STATEMENT OF ELIZABETH A. PALMER

I am a patient of Dr. Kirk Morgan with the "Patient Advocate Group for Patient's Rights in Health Care." I am writing this letter to let you know how happy I am with my treatment of Chelation Therapy and Hydrogen Peroxide and Mineral buildup given to me by Dr. Kirk Morgan.

I have had severe Rheumatoid Arthritis for 15 years and have had treatment from 8 different doctors — 3 Rheumatologist doctors, 3 Internal Medicine Specialists, and 2 Infectious

Disease Specialists. The following are a few of my experiences with these doctors: An Infectious Disease Specialist said "I want you to spit in a sputum cup," and I said "I can't spit because I don't have any saliva in my mouth." He seemed angered and said "How can I sent it to the lab to be analyzed?" Silence for a few minutes and then he got out of his chair and said "Well you're wasting my time and I'm taking up yours." No prescription, no future appointment, no advice, no help, and 15 minutes of his time cost me $180. I said to one of the Internal Medicine Specialists "I have Sjogren's Syndrome, can you help me?" and he said "Who told you that you had Sjogren's Syndrome?" I said to him "The eye doctor you sent me to." Thinking in silence a few minutes, he said "Go to the front desk and make an appointment for 3 months from now and if you haven't gained 20 pounds, I will put a tube down your throat and force feed you." I was in my wheelchair in the elevator and I started crying and my husband patted me on top of my almost bald head and said, "It's okay, he's fired and we'll keep looking until we find someone who can help you." Those doctors have prescribed 24 anti-inflammatory drugs. Cortisone and antibiotics have destroyed my immune system and caused candida albicans (Sicca), commonly known as yeast infections, and Sjogren's Syndrome (pronounced Show-grens). My symptoms include:

- headaches
- fatigue
- depression
- irritability
- digestive disorders
- respiratory disorders
- fungus infection of the toenails and fingernails (toenails & fingernails fell off)
- lesions on legs, arms and back the size of a dime
- inflamed nodules the size of marbles on hands, wrists, elbows, knees, ankles and shins
- swelling of muscles and joints that caused pain that put me to bed for days with muscle weakness
- numbness
- burning hot skin and itching tingling feeling due to not producing enough oxygen in my skin and blood
- hot and cold sweats
- lost fluid in eyes, ears and nose and did not have enough saliva to digest my food
- vomited everyday for 6 months, had constant diarrhea, lost 40 pounds and became so weak I became bedridden and could not sit up by myself or take care of myself
- excessive hair loss

I was a dying person when I found Dr. Kirk Morgan. Chelation Therapy and Hydrogen Peroxide treatments have worked like a miracle without any side effects. My sick symptoms are gone, my nails have grown back, my lesions have cleared up, the nodules are gone, my frozen hands and fingers are moving. I am eating meat now, which I could not digest for two years. I have gained back 10 pounds. I am now walking with a walker, my hair has grown back thicker than it was before and my yeast infection which started in 1990 is cleared up. My Sjogren's Syndrome is cured. I believe Dr. Morgan saved my life, and am so thankful I found him. He is a doctor who can treat my diseases to my satisfaction. I have been going to Dr. Morgan for 11 months and am a happy, healthier patient than I was before that time. I feel it is my right as a patient to choose the doctor and the treatment that is best for me. One year ago I could not have written a letter or signed my name.

ATILLA SUNAY, M.D.
P. O. Box 68
CAVE SPRING, GEORGIA 30124

May 25, 1982

Re: Ms. Elizabeth Palmer

Patient first presented to our office on 8-14-79 with a history of 3 year acute onset during the night with both knees swollen and hot. She was unable to move. Sed. Rate was 140 and she was treated with 20 Aspirin daily, Motrin, and Valium. She presented to us with symm. swelling of ankles, knees, wrist, elbows, and shoulder pain. She had been on no medicine for the past year but had taken mega-dose vitamins and strict diet control. She was in good health generally. All joint were Full ROM except both thumbs which were frozen.

She was treated with Panasol 5mg Prednisone, Durasi (antacid), and Acucron (Muscle relaxant). She did fairly well with only slight soreness, fatigue, and an occ. flare-up consistent with Rheumatoid Arthritis.

On 4-13-81 pt. stated she was having "muscle attacks" every week involving the entire body with fever and rigors. She states during the attacks she is in severe pain and unable to move. Her medicine remained the same. Gradually the attacks lengthened intervals until only 1 every month.

On 2-8-82 pt. had become moon faced with trunkal obesity. The prednisone was tapered and repalaced with a NSAID. The patient suffered a severe acute flare which she was bed-reddened for 40 days. She was seen on 3-22-82 with an episode of vascular collapse. The cortisone level was within normal limits. Pt. was re-hydrated and did very well. The medicines were changed to Cupramine, Durasil, Acucron, and Tri-Hemic.

Ms. Palmer returned on 4-12-82 without significant improvement. Her LE prep returned POSITIVE. She was last seen on 4-15-82 with the medicines of the following:

Motrin 600mg 1bid
Durasil 1 tid
Acucron 1 qid
Tri-Hemic 1daily

We feel Ms. Palmer would greatly benefit from P.T. as well as having a Medical Social Worker to help and advise of the financial status. We are looking forward to seeing the results and prognosis of this difficult case.

If I can be of any further assistance, please feel free to call.

Ms. Deborah D. Howell
Physicians Asst-C

Ms. D. Howell PA-C

DISCHARGE SUMMARY

Pat. Name	Room No.	Hosp. No.
Palmer, Elizabeth		G-2163
Attending Physician	**Date of Admission**	**Date of Discharge**
Dr. Sunay	1-10-83	1-13-83

Provisional Diagnosis: Acute sciatica and rheumatoid arthritis.

Final Diagnosis: Same

Operation: none

Brief History and Essential Physical Findings:
This is a 53 year old female admitted with acute sciatica and rheumatoid arthritis. She was recently having acute exacerbation of the arthritis. She has recently undergone conversion to lupus erythematous and she was treated at my office for 10 years. Recently she became resistent to all non-steroids, anti-arthritics including even Prednisone and Cortisone. She is relieved some by Oraflex but was switched to Feldene and she had been doing fairly well until recently when she has had a severe epigode of sudden swelling of the ankle, wrists, elbows, severe pain on the right side of her legs going into the knee and ankle. She is admitted for treatment.

Significant Laboratory, X-ray and Consultation Findings:
Her serial metabolic studies showed elevated blood sugar but this is probably due to I.V. medications. Albumin was normal as well as slight increased SGOT; Alk. phos, and SGPT. Phosphorus was within normal limits as well as 2 LE screens were essentially normal. Hemoglobin was 9.2 and urine was normal except for occasional squamous cells and trace of bacteria. Sed rate was 150 which was high. RA test was postive. Uric acid was 5 grams, Calcium was 8. Anti-DNA antibody was 13 units (0-25 is normal)C reactive protein is positive. Complement C3 is 137 which is high (50-120). Complement C 4 is normal. After 2 pints of packed cells, hemoglobin went up to 11.3. ANA is positive to 1:40. Heart was slightly enlarged and EKG showed ST depression.

Course in Hospital with Complications, if any:
The patient was started right away on Sustacal as well as I.V. fluids, 1000 cc's D5 RL with 500 mg. Solucortef and 12.5 Ascorbic acid daily for 3 days, Feldene and Magnatherm to the lower back. Patient's condition improved and she was able to move around, get up out of bed and walk around by 1-13-83 when she was discharged.

Condition, Treatment, Final Disposition on Discharge and Prognosis:
She was improving and was discharged taking Feldene and Darvocet and will be seen in the offic in 3 months.

Date 1-13-83
dict. and trans. 3-23-83
(VM)

Signed _____ M.D.

[Additional material is retained in the files of the committee.]

STATEMENT OF PATRICIA D. ROTH

I am a patient of Dr. Kirk Morgan with the "Patient Advocate Group for Patient's Rights in Health Care." I am writing this letter to let you know how happy I am with my treatment of Chelation Therapy given to me by Dr. Kirk Morgan.

I had high blood pressure (which was never below 90) for the past 40 years. I took 25 mg. a day to keep it under control, which did not work. My cholesterol was very high, my

triglycerins were high and I was also becoming a severe diabetic (which medication of 25 mg. twice a day did not control or keep it under 300 a day). I found Dr. Morgan with his treatment of Chelation—now my diabetes, cholesterol, triglycerins and blood pressure are all normal. I am taking no medication at all for the above.

I think all patients have the right to choose their doctor for treatment they are happy with. In my case it has improved the quality of my life. Dr. Morgan is concerned for all of his patients. He has done wonderful work to maintain a good life for people who would otherwise be dead now. Thanks to Dr. Morgan's treatment, I feel 20 years younger than I currently am.

STATEMENT OF LEO MODZINSKI

Leo Modzinski

Dear Senator:
I have treated Myself and A Multitude of Patients with Thousands of Chelation I.Vs Since 1972. No Deaths, All patients Improved, Prevented Costly Hospitalizations & By Pass Surgeries All Patients Treated Lived Happier More Useful Lives. Please continue This Access for Alternative Therapy for Myself and My Patients

STATEMENT OF PEARL SCHMITT

June 12 1994

To Whom it May Concern,

My purpose is to demonstrate that herbs & vitamins, chiropractic and other alternative health care are very important to me.

I can purchase those I need that are helpful to me and I want to continue to be able to do so.

My condition includes a knee injury, osteoporosis and resulting back pain I've had as pain in my knee.

Two years ago I was in very severe pain — & very movement was excruciating — With the use of herbs I was able to sleep and rest despite my pain.

With patience and education about herbs I now am walking two miles a day — I keep a shop (health food) open ten hours a day, six days a week and I feel better than I did 30 years ago — before I knew about alternative health care.

Sincerely,
Pearl Schmitt
Spokane, WA 99205

STATEMENT OF JOHN M. GUNNING

Health Care is the Buzz-word today.

Years ago in the 30's - 40's people went to a family doctor for everything, from colds to tonsils and paid out of their pockets.

Since Social Security's inception workers with an S. S. Card number had an automatic deduction from their paychecks, that was used in case of a lay-off unemployment situation. This fund today could have an additional deduction as a tax free - interest bearing account for medical needs of individuals or as a family Circle.

I, for one, have Social Security which I presently pay into at the age of 64. I am a retired policeman and as such pay $150.00 a month into our Clinic.

Other than that I am under going "Chelation Therapy" as a preventative so that something down the road doesn't hit me. Chelation Therapy was first introduced into the United States around 1944 and has been sanctioned by the A.M.A. presently for the removal of lead from the bodies of children who swallowed painted wood work in homes. The use of E.D.T.A. (ETHYLENE - DIAMINE - TETRA - ACETATE) in the Chelation process removes toxic metals and Calcium that form plaque in the arteries and there by promote better Circulation. Chelation is a maintenance program for life, once a month at a cost of about $100.00 a visit but by far exceeds the cost of a 2nd - bypass ($100,000) price tag which may last only 4 - 6 years before another operation is needed.

There in lies the culprit, wasteful surgical fees as to good health,

Chelation Therapy should be a choice whatever Medical plan may be adopted and included in as such,

[Whereupon, at 12:57 p.m., the committee was adjourned.]

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